

**HEALTH SERVICES AND DEVELOPMENT AGENCY MEETING  
DECEMBER 17, 2014  
APPLICATION SUMMARY**

NAME OF PROJECT: Morristown - Hamblen Hospital

PROJECT NUMBER: CN1410-043

ADDRESS: 908 West Fourth North Street  
Morristown (Hamblen County), TN 37814

LEGAL OWNER: Morristown - Hamblen Hospital Association  
908 West Fourth Street  
Morristown, TN 37814

OPERATING ENTITY: Not Applicable

CONTACT PERSON: Mike Richardson  
(865) 531-5123

DATE FILED: October 13, 2014

PROJECT COST: \$328,900.00

FINANCING: Cash Reserves

PURPOSE FOR FILING: Initiation of mobile Extra-Corporeal Shockwave  
Lithotripsy 2 days per week

DESCRIPTION:

Morristown - Hamblen Hospital, a 167 licensed bed acute care hospital owned by Covenant Health, a non-profit corporation based in Knoxville, Tennessee that operates hospitals, outpatient diagnostic, cancer centers and other health care facilities, is seeking approval under CONSENT CALENDAR REVIEW to initiate a mobile Extra-Corporeal Shockwave Lithotripsy (ESWL or Lithotripsy) service 2 days per week using existing operating room resources on its main campus. The project involves the lease of an existing mobile ESWL unit being used by nearby Lakeway Regional Hospital in Morristown, approximately 1 mile from the applicant's facility. The project does not involve any renovation or new construction.

SPECIFIC CRITERIA AND STANDARDS REVIEW:  
EXTRA-CORPOREAL SHOCKWAVE LITHOTRIPSY

1. **Determination of Need:** The need for ESWL services is determined by applying the following formula:

$$N = (U \times P) + O$$

N = number of ESWL services procedures needed in a Service Area;

U = latest available Tennessee use rate (number of procedures performed per 1,000 population in the state as determined by the Tennessee Department of Health);

P = projection of population (in thousands) in the service area as determined by the Tennessee Department of Health for Tennessee counties and the United States Census Bureau for non-Tennessee counties; and

O = the number of out-of-state resident procedures performed within the applicant's Service Area in the same time frame used to determine U based upon publically reported data. The applicant should document the methodology used to count volume in out-of-state resident procedures and, if different from the definition of "procedure" described in these standards and criteria, should distinguish out-of-state procedures from in-state cases.

The need shall be based upon the Service Area's current year's population projected three years forward.

*Using estimates of need for ESWL services published by Health Statistics, TDH, the applicant identified the use rate, population and estimated need for the primary service area (PSA), including Hamblen, Grainger, Claiborne, Jefferson and Cocke Counties. The need in the PSA is estimated at 298 lithotripsy procedures in calendar year (CY) 2017.*

*The applicant meets this criterion.*

2. **Minimum Volume Standard:** Applicants proposing to acquire and operate an ESWL services unit must project a minimum utilization of at least 250 procedures per year by the third year of operation, based on

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full-time use of an ESWL unit. The applicant must also document and provide data supporting the methodology used to project the patient utilization. An application to provide ESWL services on a part-time basis shall convert its projected use to that of a full-time equivalent ESWL unit.

*The applicant estimates 52 total procedures in Year 1, 78 in Year 2 and 104 in Year 3 for its proposed 2 day per week mobile service.*

*When pro-rated for the unit's part time use as described on pages 21 and 22 of the application, the target minimum volume standard for the 2 day per week mobile service is approximately 1.37 procedures per week. The applicant expects to average 1 procedure per week in Year 1, 1.5 procedures per week in Year 2 and 2 procedures per week in Year 3.*

*The projected utilization of the mobile service meets this criterion.*

- 3. Current Service Area Utilization:** The applicant should document that all existing providers of ESWL services within the proposed Service Area each performed at least 300 ESWL procedures per year during the most recent 12 month period for which data are available. The utilization by ESWL units that operate on a part-time basis shall be converted to that of a full-time equivalent ESWL unit. To characterize existing providers located within Tennessee, the applicant should use data provided by the Health Services and Development Agency. To characterize providers located outside of Tennessee, the applicant should use publicly available data, if available, and describe in its application the methodology these providers use to count volume.

In addition, the applicant should provide the HSDA with a report of patient destination for ESWL services based on the most recent 12 months of publicly reported data. This report should list all facilities that provided ESWL services to residents of the proposed Service Area and the number of ESWL procedures performed on residents of the Service Area for each facility. The Tennessee Department of Health will assist applicants in generating this report utilizing the HDDS.

*Using data from the HSDA Equipment Registry, the applicant identified Lakeway Regional Hospital (LRH) in Morristown as the only existing lithotripsy service provider that has been in operation in its 5-county primary service area since 1997*

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(CN9705-039A). LRH's mobile lithotripsy service has been significantly declining over the most recent 4 years, from 118 procedures in CY2010 to only 6 procedures in CY2013.

Using HSDA Equipment Registry data pertaining to patient destinations for ESWL services, residents of the applicant's proposed 5-county PSA had approximately 293 lithotripsy procedures in CY2013. Of this amount, 282 procedures or 96.2% were performed at provider sites in Knox County.

The applicant does not meet this criterion. The existing hospital ESWL provider's utilization is below the ESWL utilization standard.

4. **Adverse Impact on Existing Providers:** An application for ESWL services should not be approved if the new program will cause the annual caseload of existing ESWL programs within the Service Area to drop below an average of 300 procedures. The utilization by ESWL units that operate on a part-time basis shall be converted to that of a full-time equivalent ESWL unit. The patient origin study conducted for Standard 2, an analysis of patient origin data collected for Standard 3, and the referral data documented for Standard 3 should be used to determine whether such an adverse impact on existing providers is likely to occur.

The applicant provided a copy of a 7/22/14 letter from the Chief Executive Officer of Lakeway Hospital who acknowledged the CON proposal. The CEO stated that the hospital would not oppose this application.

The applicant meets this criterion. Given Lakeway Regional Hospital utilization of 6 procedures in CY2013, the project cannot drop its utilization below 300 procedures per year.

5. **Adequate Staffing and Services:** The applicant should document a plan for recruiting and maintaining a sufficient number of qualified professional and technical staff to provide the ESWL services and must document the following:
  - a. The existence of an active radiology service and an established referral urological practice;

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- b. The availability within 90 minutes' drive time of acute inpatient services for patients who experience complications; and
- c. The fact that all individuals using the equipment meet the training and credentialing requirements of the American College of Surgeons' Advisory Council for Urology.

The applicant should also document an ongoing educational plan for all staff included in the ESWL services program.

*The applicant documented the qualifications of its physician medical staff participating in the service, its plans to meet and exceed the requirements of the American College of Surgeons' Advisory Council for Urology and the training requirements provided by the ESWL unit equipment vendor (Medispec, LTD).*

*The applicant will meet this criterion.*

- 6. **ESWL Equipment:** Only applications that provide for the provision of ESWL services using equipment that has been approved by the United States Food and Drug Administration for clinical use shall be approvable.

*The proposed mobile unit is an Econolith E3000 mobile unit that received FDA approval on May 4, 2004. The applicant's proposed mobile unit was manufactured in November 2011 and has a useful life of approximately 10 years. Documentation of FDA approval is provided in the application. A detailed description of the unit is provided in Item 7 of the 10/24/14 supplemental response.*

*The applicant meets this criterion.*

- 7. **Quality Control and Monitoring:** The applicant should identify and document its intention to participate in a data reporting, quality improvement, outcome monitoring, and peer review system that benchmarks outcomes based on national norms. The system should provide for peer review among professionals practicing in facilities and programs other than the applicant.

*The applicant's plans to develop, implement and maintain clinical policies and procedures for the proposed hospital service line were addressed on page 25 of the application. The policies and procedures will be developed to incorporate TDH licensing and Joint Commission Accreditation requirements.*

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*It appears that the applicant will meet this criterion.*

- 8. Data Requirements:** Applicants should agree to provide the Department of Health and/or the HSDA with all reasonably requested information and statistical data related to the operation and provision of services and to report that data in the time and format requested. As a standard of practice, existing data reporting streams will be relied upon and adapted over time to collect all needed information.

*The applicant and affiliated hospitals of its parent company are in compliance with HSDA Equipment Registry reporting requirements. Additionally, the applicant hospital has submitted most recent Joint Annual Report as required by TDH. The applicant states that it will provide accurate and timely statistics regarding the proposed ESWL service and other data as required.*

*The applicant will meet this criterion.*

- 9. Transfer and/or Affiliation Agreements:** If an applicant is not a designated Level 1 trauma center, an applicant must document an acceptable plan for the development of transfer and/or affiliation agreements with hospitals in the service area (this criterion does not preclude the development of transfer agreements with facilities outside the applicant's Service Area).

*The applicant is a community hospital with a 24/7 emergency department that had 36,831 total ED visits as reported in the 2013 JAR. The hospital has an existing transfer agreement with UT Medical Center in Knoxville, the closest Level 1 Trauma Center hospital located approximately 52 miles from Morristown. Per the clarification provided on page 14 of the 10/24/14 supplemental response, the transfer agreement will apply to patients of the hospital's proposed mobile ESWL service.*

*The applicant meets this criterion.*

- 10. Access:** In addition to the factors set forth in HSDA Rule 0720-11-.01 (1) (listing the factors concerning need on which an application may be evaluated), the HSDA may choose to give special consideration to an applicant:

- a. That is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;

*All or portions of the 5-county service area are designated medically underserved areas (as clarified in the 10/24/14 supplemental response).*

- b. That documents that the service area population experiences a prevalence and/or incidence of urinary stones or other clinical conditions applicable to extra-corporeal shock wave lithotripsy services that is substantially higher than the State of Tennessee average; or

*The table on page 15 of the 10/24/14 supplemental response identifies the ESWL use rate for residents of the PSA. Except for Claiborne County, the applicant's service area had a higher ESWL use rate than the statewide average rate in 2013. Additional information was provided by the hospital pertaining to kidney stone cases referred by its medical staff or triaged through the hospital ED.*

- c. That is a "safety net hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program.

*Not applicable.*

*It appears that the applicant meets 2 of 3 of the criteria for this section.*

### **Staff Summary**

*The following information is a summary of the original application and all supplemental responses. Any staff comments or notes, if applicable, will be in bold italics.*

Morristown - Hamblen Hospital (MHA), a 167 licensed bed hospital at 908 West Fourth North Street in Morristown, Tennessee, is seeking CONSENT CALENDAR approval to initiate a mobile Extra-Corporeal Shockwave Lithotripsy (ESWL or lithotripsy) service on its campus 2 days per week. If approved, the service will operate out of existing operating room suites of the hospital. No renovation or new construction costs will be necessary. The hours and days of operation will be Tuesdays, Noon - 5:00 PM and Fridays, Noon - 5:00 PM. The applicant plans to initiate the proposed mobile ESWL service on or before February 15, 2015.

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The applicant plans to lease an existing Econolith E3000 lithotripsy unit owned by Medispec, Inc. that is being used occasionally by nearby Lakeway Regional Hospital in Morristown (approximately 1 mile from the applicant) as approved in CN9705-039A. The utilization of Lakeway's leased mobile unit is low and has been declining for the most recent 4 years, from 118 procedures in CY2010 to 6 procedures in CY2013. Due to the proximity between Lakeway and the applicant, an arrangement between the equipment vendor and the 2 hospitals has been discussed that would accommodate the unit's operation at both hospitals on different days of the week. A letter from the CEO of Lakeway Regional Hospital was provided with the application stating that the hospital would not oppose the project.

Morristown Hamblen Hospital's total licensed bed complement consists of 167 licensed hospital beds as follows: 55 medical, 20 surgical, 42 obstetrical, 20 ICU/CCU, 6 neonatal, 12 Pediatric and 12 geriatric psychiatric beds. Of the 167 licensed beds, 151 are presently staffed, from 159 staffed beds in CY2013 (Joint Annual Report). Based on 27,985 total inpatient days, the hospital's licensed and staffed hospital bed occupancy was 46% and 48.2%, respectively, during the period. According to the Department of Health and pertaining to the Joint Annual Reports, the following defines the two bed categories:

*Licensed Beds- The maximum number of beds authorized by the appropriate state licensing (certifying) agency or regulated by a federal agency. This figure is broken down into adult and pediatric beds and licensed bassinets (neonatal intensive or intermediate care bassinets).*

*Staffed Beds-The total number of adult and pediatric beds set up, staffed and in use at the end of the reporting period. This number should be less than or equal to the number of licensed beds.*

#### **Ownership**

- The applicant is owned by Morristown - Hamblen Hospital Association and has been a wholly owned subsidiary of Covenant Health since July 2010. The parent company is a Tennessee non-profit corporation formed in January 1952 whose corporate headquarters is in Knoxville, TN.
- As noted on page 3 of the application, Covenant Health owns and operates 9 hospitals with facilities located in Anderson, Claiborne, Cumberland, Hamblen, Knox (2), Loudon, Roane and Sevier Counties. Covenant also operates outpatient diagnostic, behavioral health and other health care related ventures in Tennessee.
- Attachment A.4 contains an organizational chart and a list of facilities owned by Covenant Health

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### **Facility Information**

- Lakeway Regional Hospital and the applicant will be the only providers of ESWL services in Hamblen County.
- The applicant's ESWL mobile unit service will be under the clinical leadership of Dr. Serbin, a board certified urologist.
- Dr. Serbin will work closely with other members of MHH's medical staff, including the Chief of Staff and Emergency Department's medical director. Letters of support for the project from Dr. Serbin and these individuals are provided in the application.
- The service will utilize existing operating room space of the hospital's surgery department located on the 2<sup>nd</sup> floor of the hospital. The department's physical plant includes 6 operating rooms, recovery and isolation areas, a nursing station, sterile storage/processing, patient areas and staff support areas.
- The surgery department is in close proximity to the hospital ED on the same side of the main hospital building.
- Operating Room #5 appears to be the preferred location for the ESWL mobile unit for reasons explained in Item 5 of the 10/24/14 supplemental response. The applicant states this area is the most flexible option for ESWL procedures that does not disrupt other operations of the Surgery Department.
- The applicant states no renovation or new construction will be necessary to accommodate the mobile unit.
- A floor plan drawing of the proposed site is included as Attachment B.IV.

### **Mobile ESWL Equipment**

- Proposed Econolith E3000 mobile lithotripsy unit owned by Medispec, Inc. was manufactured in November 2011 and first used at Lakeway Regional Hospital in 2012.
- As noted in Item 7 of the 10/24/14 supplemental response, Medispec plans to work with Lakeway to amend their current ESWL agreement in order to coordinate treatment schedules and share the mobile unit with the applicant.
- The unit has several state of the art technological advantages, including features that provide enhanced targeting accuracy and power.
- The applicant states that the unit has a relatively high "stone free" success rate averaging 82.9%.
- The vendor quote documents a 3-year lease cost of \$315,900.00 which is based on a \$1,350 per procedure or "per click" rate. This amount is higher than the ESWL unit's estimated fair market value of \$245,000.00. The expiration date of the vendor quote is 1/31/2015.

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### Project Need

The applicant identified the need for the project using ESWL estimates developed by TDH for the 5-county service area and HSDA Equipment Registry data pertaining to ESWL patient volumes by county of residence. In light of this information, the applicant believes there is a need to improve access to ESWL services and reduce high outmigration to ESWL providers outside the service area. The information is illustrated in the table below.

**Service Area ESWL Projected Need Compared to Resident Use**

County	2017 Population	Estimated Need (ESWL Procedures)	Resident Procedures (2013)	Resident Procedures at Knox County Sites (2013)
Hamblen	65,181	90	80	77
Cocke	38,143	53	51	50
Claiborne	33,110	46	34	32
Grainger	23,513	32	34	32
Jefferson	56,054	77	94	91
<b>Total</b>	<b>216,001</b>	<b>298</b>	<b>293</b>	<b>282</b>

Sources: Estimate of Need by County, 8/14 TDH document; ESWL patient origin data, HSDA Equipment Registry

The following items summarize the need for the project:

- Enhance access of residents in service area to mobile ESWL service through coordination of patient referrals with physician specialists and the hospital ED.
- Reduce inordinately high levels of resident outmigration to more distant ESWL providers, primarily hospitals located in Knox County an average of 110 miles round trip from Morristown.
- Continue commitment to efficient and cost effective full hospital service lines.
- Maximize use of existing, modern ESWL mobile unit that is in operation but underutilized by residents of the service area .

### Applicant's ESWL Service Area

The primary service area of the applicant's proposed new lithotripsy service is Hamblen County while Cocke, Claiborne, Grainger and Jefferson Counties comprise the secondary service area. Collectively, these counties accounted for the majority of the hospital's patient volumes in 2013 (inpatients, outpatients and emergency department patients). The volumes by patient origin are illustrated in the tables on pages 29 and 30 of the application.

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- Per the TDH summary report, the total population of the combined 5-county service area is estimated at 210,314 residents in calendar year 2014 increasing by approximately 2.7% to 216,001 residents in CY 2017.
- The total population of the state of Tennessee is expected to grow 2.77% from CY2014 to CY2017.
- The total 65+ age population is estimated at 37,994 residents in CY 2014 increasing approximately 6.4% to 40,422 residents in 2017 compared to a statewide change of 9.16% during this time period.
- The age 65 and older population accounts for approximately 18.1% of the total service area population compared to 15.8% statewide.
- As noted in Item 4 of the 10/24/14 supplemental response, the applicant estimates that approximately 22.6% of the service area's residents are enrolled in TennCare compared to 18.8% statewide.

### Historical and Projected Utilization

Morristown - Hamblen Hospital is seeking approval to initiate a new mobile lithotripsy service 2 days per week on its outpatient campus in a 5-county primary and secondary service area (PSA/SSA) that has 1 mobile ESWL provider, Lakeway Regional Hospital (Lakeway) in Morristown. The utilization of the Lakeway unit is shown in the table provided in Attachment C.1.a.3 of the application. As noted, the utilization of Lakeway's mobile ESWL service is declining. Data available for the most recent 4-year period indicates that Lakeway performed 118 procedures in CY2010, 18 in CY2011, 42 in CY2012 and 6 procedures in CY2013. Of these, TennCare recipients accounted for an average of approximately 45% of the total number of annual ESWL procedures during the period.

Residents of the service area are leaving in large numbers for ESWL providers elsewhere in Tennessee, primarily Knox County providers. The outmigration to other providers is shown in the table below.

**ESWL Provider Utilization by PSA Residents**

	2011	2012	2013	% Change '11-'13
Total ESWL Procedures by Residents of PSA	252	268	293	16.3%
PSA Resident Procedures at Knox County ESWL Providers (as a % of total)	234 (93%)	261 (97%)	282 (96%)	20.5%
Knox County ESWL provider procedures	1,536	1,490	1,592	3.6%
% by PSA Residents	15%	18%	18%	NA

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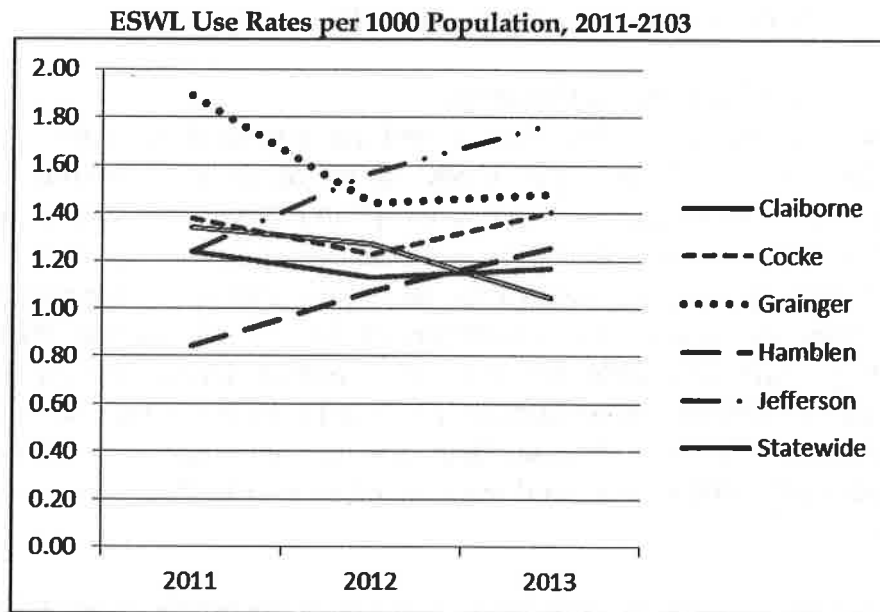
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The use rate by service area residents (Lithotripsy procedures per 1,000 population) compared to the statewide resident use rate from 2010 - 2013 is illustrated in the tables below.

**ESWL Use Rates per 1,000 Population in MHHA's Service Area**

County	2011	2012	2013
Cocke	1.38	1.22	1.40
Claiborne	1.34	1.27	1.05
Grainger	1.89	1.44	1.48
Hamblen (PSA)	0.84	1.07	1.25
Jefferson	1.24	1.57	1.77
Statewide	1.24	1.13	1.17



Source: HSDA Equipment Registry as of 11/4/14

Based on the tables above, the following highlights are noted:

- On average, approximately 96% of area residents' total ESWL procedures were performed at Knox County provider sites from 2011 - 2013.
- Knox County ESWL provider dependence on residents of the applicant's service area was approximately 16% of Knox County provider volumes from 2011 to 2013.
- The chart and trend line graph reflects that resident ESWL use rates of the service area, excluding Claiborne County, and the statewide use rate appear to be trending upward during the period.
- Of the 5 service area counties, all but Claiborne County were higher than the statewide rate from 2011 - 2013.

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The applicant projects 52 procedures in Year 1 increasing to 78 procedures in Year 2. The projected utilization is based on a "recapture rate" of approximately 20% of the resident ESWL procedures performed at providers outside the service area. As noted in the tables on page 5 of the TDH summary, the applicant's projected utilization will exceed the minimum ESWL standards by Year 2 of the project. Utilization is estimated at approximately 110% of the standard in Year 2 increasing to 146% of the standard in Year 3 of the project.

### **Project Cost**

Major costs are:

- Lease of Econolith E3000 lithotripsy unit over 3 years at a per click rate of \$1,350 per procedure. Total payments are estimated at approximately \$315,900 (96% of the total project cost).
- There are no costs for renovation or new construction associated with this project.
- For other details on Project Cost, see the revised Project Cost Chart on page 38-R of the original application.

### **Historical Data Chart**

The ESWL service is a new service line for the hospital with no record of fiscal operations. Highlights of the applicant's overall financial performance are as follows:

- According to the revised Historical Data Chart MHH reported the following net operating income; a loss of \$2,977,428.00 in CY2011 after deductions for depreciation, interest, taxes and management fees. NOI improved in the following 2 consecutive fiscal years periods to \$3,561,967.00 in CY2013 for a favorable margin of approximately 1.3% of gross operating revenues.
- In the course of HSDA staff review of the application, there appeared to be a difference of approximately \$9 million in deductions for charity and bad debt as reported in the Historical Data Chart and Income Statement compared to what was reported in the applicant's 2013 Joint Annual Report. The applicant explained that the reason for the difference is due to estimated reserves of uncollected revenue in the hospital's operating statements. Please see the clarification provided in Item 14 of the 10/24/14 supplemental response.

### **Projected Data Chart**

Total gross operating revenue of the applicant's new mobile lithotripsy service is \$779,393.00 in on 52 procedures in Year 1 increasing by approximately 50.1% to \$1,169,089.00 on 78 procedures in Year Two. The Projected Data Chart reflects the following:

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- Net operating income amounts to \$50,404.00 in Year 1 and \$75,607.00 in Year 2.
- The operating margin of the new ESWL service amounts to approximately 6.5% of gross revenue in Year 2.
- Net operating revenue drops to approximately 25% of gross operating revenue, largely due to the high amount estimated for contractual adjustments from charges. The combined Medicare/TennCare payor mix of 78% of gross operating revenue may help explain why contractual adjustments are higher for this service.

### **Charges**

As clarified in Item 15 of the 10/24/14 supplemental response, the average gross charge of \$14,988.00 per procedure is based on fees for ESWL services at other Covenant Hospitals with mobile units. A summary of the applicant's charges for Year 1 of the project is as follows:

- The proposed average net charge is \$3,828.00 per procedure.
- The Medicare allowable charge for the most common ESWL procedures at community hospitals like the applicant range from \$2,484/procedure - \$8,334/procedure.
- According to the HSDA Equipment Registry, the applicant's \$14,988.00 gross charge falls between the 2013 ESWL median charge of \$12,783.82 and the 3<sup>rd</sup> quartile charge of \$17,953.48.
- As noted on page 22 of the 10/24/14 supplemental response, the applicant states that the proposed gross is lower than lithotripsy projects approved by HSDA in 2013, ranging from a low of \$17,842.00 (Physician's Regional Medical Center) to a high of approximately \$32,456.00 (Lakeway Regional Hospital).

### **Payor Mix**

- The expected payor mix in Year 1 includes 57% of gross operating revenue for Medicare and 15% for TennCare.
- The hospital contracts with all TennCare MCOs in the service area: United Healthcare Community Plan and Blue Care.
- The applicant's self-pay payor mix is approximately 7% of gross operating revenue in Year 1.

### **Financing**

- While there is no significant capital outlay or start-up costs for the project, the parent company will provide funding support from cash reserves if necessary.

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- A letter dated October 1, 2014 from the CFO of the parent company confirms that Covenant Health has sufficient cash reserves to fund the project, as appropriate.
- Review of the hospital's Balance Sheet for the period ending December 31, 2013 revealed \$219,763,000 in total current assets, total current liabilities of \$197,552,000 and a current ratio of 1.11 to 1.0.
- *Note to Agency Members: current ratio is a measure of liquidity and is the ratio of current assets to current liabilities which measures the ability of an entity to cover its current liabilities with its existing current assets. A ratio of 1:1 would be required to have the minimum amount of assets needed to cover current liabilities.*

### **Staffing**

- The service will be under the clinical leadership of Philip Serbin, M.D., a board certified urologist, in collaboration with the Chief of the Medical Staff and the medical director of the hospital's emergency department.
- The proposed staffing pattern of the service consists of 4 position classifications including a surgery Registered Nurse (RN), a post-operative RN, a surgery technician and administrative staff.
- As clarified in Item 17 of the supplemental response, each of the employee types involved with the proposed mobile ESWL service will work on a regular hour basis equivalent to less than 5% of the 2,080 regular hours typically worked by a full time employee (FTE).

### **Licensure/Accreditation**

- Morristown - Hamblen is accredited by The Joint Commission and licensed by TDH.

*The applicant has submitted the required information on corporate documentation, site control and a quote for the 3-year lease of the mobile ESWL unit that will be effective on the date of the Agency hearing of the application. Staff will have a copy of these documents available for member reference at the meeting. Copies are also available for review at the Health Services and Development Agency's office.*

Should the Agency vote to approve this project, the CON would expire in three years.

### **CERTIFICATE OF NEED INFORMATION FOR THE APPLICANT:**

There are no other Letters of Intent, denied or pending applications for this applicant.

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**Outstanding Certificates of Need**

**Morristown Hamblen Hospital, CN1009-040AE**, has an outstanding Certificate of the Need that will expire on February 1, 2015. The project was approved at the December 15, 2010 Agency meeting for the acquisition of a combination fixed positron emission tomography/computed tomography scanner (PET/CT ) to replace its existing 3 day per week mobile PET/CT unit with an original expiration date of February 1, 2014. Two extensions of the project expiration date have been approved. The first was granted to extend the expiration date to August 1, 2014. The second was approved at the May 28, 2014 Agency meeting extending the project expiration date to February 1, 2015. The extensions were necessary due to structural issues (weight bearing) with the original location which was subsequently changed to another area of the hospital. The estimated project cost is **\$4,695,707.00**. *Project Status Update: the applicant reported on 10/24/14 that the project is nearing completion by the expiration date of 2/1/2015. The applicant has complied with HSDA reporting requirements. An annual project report was submitted in July 2014.*

**CERTIFICATE OF NEED INFORMATION FOR OTHER SERVICE AREA FACILITIES:**

There are no other Letters of Intent, pending or denied applications, or outstanding Certificates of Need for other health care organizations proposing this type of service.

**PLEASE REFER TO THE REPORT BY THE DEPARTMENT OF HEALTH, DIVISION OF HEALTH STATISTICS, FOR A DETAILED ANALYSIS OF THE STATUTORY CRITERIA OF NEED, ECONOMIC FEASIBILITY, AND CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE IN THE AREA FOR THIS PROJECT. THAT REPORT IS ATTACHED TO THIS SUMMARY IMMEDIATELY FOLLOWING THE COLOR DIVIDER PAGE.**

PJG  
(11/21/14)

# LETTER OF INTENT



**State of Tennessee**  
**Health Services and Development Agency**  
 Andrew Jackson Building, 9<sup>th</sup> Floor  
 502 Deaderick Street  
 Nashville, TN 37243  
[www.tn.gov/hsda](http://www.tn.gov/hsda)

Phone: 615-741-2364

Fax: 615-741-9884

## LETTER OF INTENT

The Publication of Intent is to be published in the Citizen Tribune which is a newspaper  
 of general circulation in Hamblen County, Tennessee, on or before October 10, 2014, for one day.  
 (County) (Month / day) (Year)

=====

This is to provide official notice to the Health Services and Development Agency and all Interested parties, in accordance with T.C.A. § 68-11-1601 *et seq.*, and the Rules of the Health Services and Development Agency, that:

Morristown-Hamblen Hospital

(Name of Applicant)

an Acute Care Hospital

(Facility Type-Existing)

owned by: Morristown-Hamblen Hospital Association with an ownership type of Not-for-Profit Corporation  
 and to be managed by: (Not Applicable) intends to file an application for a Certificate of Need for: \_\_\_\_\_

the initiation of Mobile Extra-Corporeal Shock Wave Lithotripsy Services using vendor-owned mobile lithotripsy medical equipment for two (2) days per week on the hospital campus at 908 West Fourth North Street in Morristown, Tennessee. The total estimated project cost is \$ 328,900.

The anticipated date of filing the application is: October 14, 2014.

The contact person for this project is Mike Richardson, Vice President, Strategic Planning & Development  
 (Contact Name) (Title)

who may be reached at: Covenant Health, 280 Fort Sanders West Boulevard, Building 4, Suite 218  
 (Company Name) (Address)

Knoxville, Tennessee 37922 865 / 531-5123  
 (City) (State) (Zip Code) (Area Code / Phone Number)

[Signature]  
 (Signature)

10-8-14  
 (Date)

mdr@covhlth.com  
 (E-mail Address)

=====

The Letter of Intent must be filed in triplicate and received between the first and the tenth day of the month. If the last day for filing is a Saturday, Sunday or State Holiday, filing must occur on the preceding business day. File this form at the following address:

Health Services and Development Agency  
 Andrew Jackson Building, 9<sup>th</sup> Floor  
 502 Deaderick Street  
 Nashville, Tennessee 37243

=====

The published Letter of Intent must contain the following statement pursuant to T.C.A. § 68-11-1607(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

**COPY**

**-Application**

**Morristown**

**Hamblen**

**Hospital**

**CN1410-043**

1. Name of Facility, Agency, or Institution**Morristown-Hamblen Hospital**

Name

**908 West Fourth North Street**

Street or Route

**Hamblen**

County

**Morristown**

City

**Tennessee**

State

**37814**

Zip Code

2. Contact Person Available for Responses to Questions**Mike Richardson**

Name

**Vice President, Strategic Planning and Development**

Title

**Covenant Health**

Company Name

**mdr@covhlth.com**

E-mail Address

**280 Fort Sanders West Blvd., Building 4, Suite 218 Knoxville**

Street or Route

City

**TN**

State

**37922**

Zip Code

**Employee of Parent Company**

Association with Owner

**(865) 531-5123**

Phone Number

**(865) 531-5729**

Fax Number

3. Owner of the Facility, Agency or Institution**Morristown-Hamblen Hospital Association**

Name

**(423) 492-5000**

Phone Number

**908 West Fourth North Street**

Street or Route

**Hamblen**

County

**Morristown**

City

**Tennessee**

State

**37814**

Zip Code

See Attachment A.3. – Corporate Charter & Certificate of Corporate Existence4. Type of Ownership of Control (Check One)

A. Sole Proprietorship

B. Partnership

C. Limited Partnership

D. Corporation (For Profit)

E. **Corporation (Not-for-Profit)****X**F. Government (State of TN or  
Political Subdivision)

G. Joint Venture

H. Limited Liability Company

I. Other (Specify)

See Attachment A.4. – Organizational Chart



Morristown-Hamblen Hospital (“MHH”) is a 167-bed not-for-profit community hospital located in Morristown, Tennessee. Effective July 1, 2010, MHH became part of the Covenant Health organization. Covenant Health is a Tennessee non-profit corporation, qualified under 501(c)(3) of the Internal Revenue Code, with its principal offices in Knoxville, Tennessee. Covenant Health is the parent corporation for a healthcare system that operates hospitals, cancer centers, and other health care facilities, and engages in many other health care related activities.

Covenant Health has one consolidated Board of Directors that governs operations, which includes representation from across the communities served by its entities. Covenant Health includes hospitals, behavioral health facilities, cancer treatment centers, various outpatient diagnostic and treatment centers, and several other healthcare related ventures. Covenant Health is the sole member of its non-profit subsidiaries and is the sole shareholder of its for-profit subsidiaries.

The following chart summarizes the *hospital* facilities currently operated by Covenant Health (licensure/certification for each hospital is current).

<i>Facility</i>	<i>Location</i>	<i>Licensed Beds</i>
Fort Sanders Regional Medical Center	1901 Clinch Avenue Knoxville, Tennessee 37916	541 (1)
Parkwest Medical Center	9352 Park West Blvd. Knoxville, Tennessee 37923	307
Methodist Medical Center of Oak Ridge	990 Oak Ridge Turnpike Oak Ridge, Tennessee 37830	301
LeConte Medical Center (replacement for Fort Sanders Sevier Medical Center)	742 Middle Creek Road Sevierville, Tennessee 37862	79 (2)
Fort Loudoun Medical Center	550 Fort Loudoun Medical Center Drive Lenoir City, Tennessee 37772	50
Roane Medical Center	8045 Roane Medical Center Drive Harriman, Tennessee 37748	54 (3)
Morristown-Hamblen Hospital	908 West Fourth North Street Morristown, Tennessee 37814	167
Cumberland Medical Center	421 South Main Street Crossville, Tennessee 38555	189
Claiborne Medical Center	1850 Old Knoxville Road Tazewell, Tennessee 37879	85 (4)
Peninsula Hospital (a division/satellite of Parkwest Medical Center)	2347 Jones Bend Road Louisville, Tennessee 37777	155

(1) License includes 517 hospital beds and 24 skilled nursing beds.

(2) Also licensed and operates 54 intermediate and skilled nursing beds.

(3) Roane Medical Center once operated 105 licensed beds, including 10 swing beds; however, the replacement hospital facility has 54 licensed beds, including 10 swing beds.

(4) The nursing home adjacent to the hospital is licensed for 100 beds.

5. **Name of Management/Operating Entity (If Applicable)****Not applicable.**

Name \_\_\_\_\_

Street or Route \_\_\_\_\_

County \_\_\_\_\_

City \_\_\_\_\_

State \_\_\_\_\_

Zip Code \_\_\_\_\_

**PUT ALL ATTACHMENTS AT THE END OF THE APPLICATION IN ORDER AND  
REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.**

6. **Legal Interest in the Site of the Institution (Check One)**

- |                         |          |                    |       |
|-------------------------|----------|--------------------|-------|
| A. Ownership            | <u>X</u> | D. Option to Lease | _____ |
| B. Option to Purchase   | _____    | E. Other (Specify) | _____ |
| C. Lease of _____ Years | _____    |                    |       |

**See Attachment A.6. – Deed**7. **Type of Institution (Check as appropriate—more than one response may apply)**

- |  |          |  |       |
|--|----------|--|-------|
| A. Hospital (Specify) Acute Care                                   | <u>X</u> | I. Nursing Home                              | _____ |
| B. Ambulatory Surgical Treatment Center (ASTC), Multi-Specialty    | _____    | J. Outpatient Diagnostic Center              | _____ |
| C. ASTC, Single Specialty  | _____    | K. Recuperation Center                       | _____ |
| D. Home Health Agency  | _____    | L. Rehabilitation Facility                   | _____ |
| E. Hospice   | _____    | M. Residential Hospice                       | _____ |
| F. Mental Health Hospital  | _____    | N. Non-Residential Methadone Facility        | _____ |
| G. Mental Health Residential Treatment Facility                    | _____    | O. Birthing Center                           | _____ |
| H. Mental Retardation Institutional Habilitation Facility (ICF/MR) | _____    | P. Other Outpatient Facility (Specify) _____ | _____ |
|  |          | Q. Other (Specify) _____                     | _____ |

8. **Purpose of Review (Check) as appropriate—more than one response may apply)**

- |  |          |   |       |
|--|----------|---|-------|
| A. New Institution   | _____    | G. Change in Bed Complement   | _____ |
| B. Replacement/Existing Facility                                       | _____    | [Please note the type of change by underlining the appropriate response: Increase, Decrease, Designation, Distribution, Conversion, Relocation] |       |
| C. Modification/Existing Facility                                      | _____    | H. Change of Location   | _____ |
| D. Initiation of Health Care Service as defined in TCA § 68-11-1607(4) | <u>X</u> | I. Other (Specify) _____  | _____ |
| (Specify): <u>Extra-Corporeal Shock Wave Lithotripsy Services</u>      |          |   |       |
| F. Discontinuance of OB Services                                       | _____    |   |       |
| Acquisition of Equipment   | _____    |   |       |

2019-14-0002

**9. Bed Complement Data*****Please indicate current and proposed distribution and certification of facility beds.***

	<u>Current Beds Licensed</u>	<u>Beds *CON</u>	<u>Staffed Beds</u>	<u>Beds Proposed</u>	<u>TOTAL Beds at Completion</u>
A. Medical	<u>55</u>		<u>48</u>		<u>55</u>
B. Surgical	<u>20</u>		<u>20</u>		<u>20</u>
C. Long-Term Care Hospital	-		-		-
D. Obstetrical/GYN	<u>42</u>		<u>39</u>		<u>42</u>
E. ICU/CCU	<u>20</u>		<u>20</u>		<u>20</u>
F. Neonatal (NICU)*	<u>6</u>		<u>0</u>		<u>6</u>
G. Pediatric	<u>12</u>		<u>12</u>		<u>12</u>
H. Adult Psychiatric	-		-		-
I. Geriatric Psychiatric	<u>12</u>		<u>12</u>		<u>12</u>
J. Child/Adolescent Psychiatric	-		-		-
K. Rehabilitation	-		-		-
L. Nursing Facility (non-Medicaid Certified)	-		-		-
M. Nursing Facility Level 1 (Medicaid only)	-		-		-
N. Nursing Facility Level 2 (Medicare only)	-		-		-
O. Nursing Facility Level 2 (dually certified Medicaid/Medicare)	-		-		-
P. ICF/MR	-		-		-
Q. Adult Chemical Dependency	-		-		-
R. Child and Adolescent Chemical Dependency	-		-		-
S. Swing Beds	-		-		-
T. Mental Health Residential Treatment	-		-		-
U. Residential Hospice	-		-		-
<b>TOTAL</b>	<b><u>167</u></b>		<b><u>151</u></b>		<b><u>167</u></b>

\*NICU services currently suspended

10. Medicare Provider Number 44-0030  
 Certification Type Acute Care Hospital

11. Medicaid Provider Number 044-0030  
 Certification Type Acute Care Hospital

12. If this is a new facility, will certification be sought for Medicare and/or Medicaid?  
 The proposed project will be part of an existing facility.

13. **Identify all TennCare Managed Care Organizations/Behavioral Health Organizations (MCOs/BHOs) operating in the proposed service area. Will this project involve the treatment of TennCare participants? Yes If the response to this item is yes, please identify all MCOs/BHOs with which the applicant has contracted or plans to contract.**

The proposed project will involve treatment of TennCare participants. Morristown-Hamblen Hospital has existing contracts with all TennCare MCOs in the area, including:

- United HealthCare Community Plan/TennCare
- Blue Care/TennCare

**Discuss any out-of-network relationships in place with MCOs/BHOs in the area.**

Not applicable.

**NOTE:** **Section B** is intended to give the applicant an opportunity to describe the project and to discuss the need that the applicant sees for the project. **Section C** addresses how the project relates to the Certificate of Need criteria of Need, Economic Feasibility, and the Contribution to the Orderly Development of Health Care. **Discussions on how the application relates to the criteria should not take place in this section unless otherwise specified.**

## **SECTION B: PROJECT DESCRIPTION**

Please answer all questions on 8 1/2" x 11" white paper, clearly typed and spaced, identified correctly and in the correct sequence. In answering, please type the question and the response. All exhibits and tables must be attached to the end of the application in correct sequence identifying the questions(s) to which they refer. If a particular question does not apply to your project, indicate "Not Applicable (NA)" after that question.

- I. Provide a brief executive summary of the project not to exceed two pages. Topics to be included in the executive summary are a brief description of proposed services and equipment, ownership structure, service area, need, existing resources, project cost, funding, financial feasibility and staffing.

### **Background: Morristown-Hamblen Hospital**

Morristown-Hamblen Hospital ("MHH") operates a not-for-profit community hospital that includes 167 licensed acute care hospital beds and offers an extensive array of needed inpatient, outpatient, and emergency services.

MHH is an important component of the TennCare provider network within the hospital's service area. Moreover, as a not-for-profit community hospital, MHH serves all patients regardless of race, ethnicity, gender, age, or income level. MHH's long history reflects a proven commitment to ongoing investments in both clinical talent and medical technology needed to better serve the evolving needs and expectations of patients and providers within the region. This project is a continuation of that commitment, as MHH seeks to expand access to mobile lithotripsy services in the project service area to benefit patients and physicians.

### Proposed Service and Equipment

Morristown-Hamblen Hospital (MHH) seeks to initiate Mobile Extra-Corporeal Shock Wave Lithotripsy Services (i.e. “lithotripsy”) to be operated two days per week on its main hospital campus to improve access to lithotripsy services within the region. The project proposes use of an existing vendor-owned mobile lithotripsy system operating within the region that has significant open capacity available to support this needed project. The proposed project will help MHH and its growing medical staff better serve many patients who present with the painful diagnosis of kidney stones:

*“Lithotripsy is defined as the pulverization of urinary stones by means of a lithotripter.*

*Extracorporeal lithotripsy is lithotripsy that occurs outside the body. Extracorporeal shock wave lithotripsy is the non-invasive procedure that uses shock waves to pulverize urinary stones, which can then be expelled in the urine. An emitter is placed in contact with the patient relative to where the stone is located and the shock waves are focused on the stone, which is shattered by the force.”*

*(Source: State Health Plan, Tennessee – Extra-Corporeal Shock Wave Lithotripsy Services)*

The proposed location of the lithotripsy service is well-known, convenient, and accessible. The MHH campus will provide a “patient-friendly” and “physician-friendly” environment for lithotripsy procedures within the region. The project represents an efficient, orderly, and effective way to relieve significant time and travel burdens for a significant and growing number of patients who seek care, and relief from acute pain, related to kidney stones. The proposed project provides an important clinical tool needed by the hospital’s growing medical staff and improves local access for community physicians and their patients.

### Attachment B.I.a. Physician Support Letters

The proposed MHH lithotripsy service will be operated as part of the hospital’s surgical department – and will be linked closely to operations of both physician practices in the service area and the hospital’s emergency department. An existing and appropriately equipped operating/procedure room within the hospital’s surgery area will be used for the project (Operating Room # 5), so no construction and/or renovation expenses will be required to complete the project.

### Project Service Area

The “primary service area” for this lithotripsy project is Hamblen County from a traditional planning standpoint. As outlined within the Service Area section of this application (Section C.3), most of MHH’s inpatients, outpatients, and emergency department patients reside in Hamblen County. Additionally, MHH and supporting physicians anticipate serving patients from other nearby counties and rural areas in the region where some MHH patients have resided historically (i.e. “secondary service area”). Therefore, the “*Project Service Area*” from a CON perspective includes Hamblen, Claiborne, Grainger, Jefferson, and Cocke Counties in East Tennessee.

The proposed mobile lithotripsy unit will enhance convenience, access, and technology for MHH patients living and working within the project service area that is marked by a growing and aging population – and relatively high levels of TennCare enrollment and poverty.

#### Existing Resources

According to the latest available data from the Health Services and Development Agency's Medical Equipment Registry, the only other approved provider of lithotripsy services in the project's service area is Lakeway Hospital (the for-profit hospital in Hamblen County operated by CHS). Although Lakeway Hospital has approval to operate mobile lithotripsy equipment seven days per week, Lakeway only performed six (6) procedures during the most recent reporting year of the HSDA Equipment Registry and the Tennessee Hospital Joint Annual Report. Several months prior to the filing of this CON application, the CHS/Lakeway leadership team provided written confirmation that they are not opposed to this needed MHH project that will be developed in an orderly manner.

See Attachment B.I.b: Letter from CHS/Lakeway Hospital

#### Need

The proposed project is needed to improve access to lithotripsy services for patients and physicians within the project service area, reduce unnecessary patient burdens (i.e. time, suffering, and travel expense) related to lithotripsy case outmigration, and to help MHH better coordinate needed patient care services locally in an optimal and orderly manner. The project will improve lithotripsy accessibility, use, and benefit within the region by initiating lithotripsy services at the well-known MHH campus.

The initiation of mobile lithotripsy services at MHH reflects an economically feasible approach to expanding access to needed services for the community. The lithotripsy services of MHH will be open and accessible to all patients and any referring physician in the region. Like all MHH services, this project will be accessible to all patients in the region since MHH is a contracted provider with all area TennCare MCOs and has a long history of serving patients regardless of race, ethnicity, gender, age, or income level. The project addresses evolving community needs and the expressed opinions of providers who serve patients from the region. This project reflects the ongoing commitment of MHH to invest in needed community healthcare resources locally – and does not create financial and legal risk for other providers.

#### Ownership Structure

The proposed project will be owned and operated by Morristown-Hamblen Hospital ("MHH"), which will be the provider of the mobile lithotripsy service. MHH is a non-profit hospital that joined Covenant Health in July 2010. Covenant Health is a Tennessee non-profit corporation, 501(c)(3), with its principal offices in Knoxville, Tennessee. Covenant Health is the parent corporation for a healthcare system that operates hospitals, cancer centers, other health care facilities, and engages in many other health care related activities.

#### Project Cost and Funding

The total estimated cost for CON purposes is \$ 328,900. This total project cost

includes a total estimated medical equipment cost of \$ 315,900 for the mobile lithotripsy equipment (which equals the sum of “per procedure lease payments” for the initial lease term – and which is greater than the documented fair market value of the lithotripsy equipment). However, no actual capital costs related to the project will be incurred by MHH or Covenant Health. The project will be funded through operational cash flow. However, the applicant has access to sufficient cash reserves to complete and support the proposed project if needed.

#### Financial Feasibility

The project is economically feasible. The positive cash flow projected for each year of the project will be sufficient to maintain operations over time. Regardless, the applicant has adequate financial resources to cover the entire cost of the project as a Covenant Health affiliate. MHH is contracted with all area TennCare MCOs and will continue to serve all patients regardless of race, ethnicity, gender, age, or income level.

#### Staffing

Initial staffing for the project will include existing hospital employees to support the mobile lithotripsy service as needed: Surgery RN (< .05 FTE); Pre/Post-Op RN (< .05 FTE); Surgery Technician (< .05 FTE), Office and Logistics Support Staff (< .05 FTE).

II. Provide a detailed narrative of the project by addressing the following items as they relate to the proposal.

- A. Describe the construction, modification and/or renovation of the facility (exclusive of major medical equipment covered by T.C.A. § 68-11-1601 et seq.) including square footage, major operational areas, room configuration, etc. Applicants with hospital projects (construction cost in excess of \$5 million) and other facility projects (construction cost in excess of \$2 million) should complete the Square Footage and Cost per Square Footage Chart. Utilizing the attached Chart, applicants with hospital projects should complete Parts A.-E. by identifying as applicable nursing units, ancillary areas, and support areas affected by this project. Provide the location of the unit/service within the existing facility along with current square footage, where, if any, the unit/service will relocate temporarily during construction and renovation, and then the location of the unit/service with proposed square footage. The total cost per square foot should provide a breakout between new construction and renovation cost per square foot. Other facility projects need only complete Parts B.-E. Please also discuss and justify the cost per square foot for this project.

If the project involves none of the above, describe the development of the proposal.

**Not applicable.** An existing and appropriate operating/procedure room within the hospital's surgery area (MHH Operating Room # 5) will be used for the project, so construction and/or renovation expenses will not be required.

The proposed site will allow operational coordination with the established service lines of MHH and virtual connectivity for affiliated providers in the region.

- B. Identify the number and type of beds increased, decreased, converted, relocated, designated, and/or redistributed by this application. Describe the reasons for change

in bed allocations and describe the impact the bed change will have on the existing services. **Not applicable.**





- C. As the applicant, describe your need to provide the following health care services (if applicable to this application):

1. Adult Psychiatric Services
2. Alcohol and Drug Treatment for Adolescents (exceeding 28 days)
3. Birthing Center
4. Burn Units
5. Cardiac Catheterization Services
6. Child and Adolescent Psychiatric Services
7. Extracorporeal Lithotripsy
8. Home Health Services
9. Hospice Services
10. Residential Hospice
11. ICF/MR Services
12. Long-term Care Services
13. Magnetic Resonance Imaging (MRI)
14. Mental Health Residential Treatment
15. Neonatal Intensive Care Unit
16. Non-Residential Methadone Treatment Centers
17. Open Heart Surgery
18. Positron Emission Tomography
19. Radiation Therapy/Linear Accelerator
20. Rehabilitation Services
21. Swing Beds

**MHH, the MHH medical staff, and community physician partners need improved access to extracorporeal shock-wave lithotripsy technology to better serve a significant and growing number of patients who seek care and relief from acute pain related to kidney stones. Project approval will enhance the clinical capabilities of MHH and aligned physicians to care for this patient population.**

**The project does not require the purchase of a new lithotripsy unit. Rather, the project seeks to establish a per-procedure (“per click”) equipment lease arrangement to utilize existing mobile lithotripsy equipment owned and operated in the service area by a proven vendor.**

**The project will utilize a modern mobile lithotripsy unit that can be easily transported across care sites by trained staff, rolled off a truck into a procedure room, and utilized to provide safe and efficient care for patients. No construction or renovation will be necessary for this project.**

- D. Describe the need to change location or replace an existing facility.

**Not applicable.**

- E. Describe the acquisition of any item of major medical equipment (as defined by the Agency Rules and the Statute) which exceeds a cost of \$ 2 million; and/or is a magnetic resonance imaging (MRI) scanner, positron emission tomography (PET) scanner, extracorporeal lithotripter and/or linear accelerator by responding to the following:

1. For fixed-site major medical equipment (not replacing existing equipment):

- a. Describe the new equipment, including:

**Not Applicable**

1. Total cost; (as defined by Agency Rule).
2. Expected useful life;
3. List of clinical applications to be provided; and
4. Documentation of FDA approval.

- b. Provide current and proposed schedules of operations.

**Not Applicable**

2. For mobile major medical equipment:

The proposed mobile lithotripsy equipment for the project will be the Medispec Econolith E3000 [i.e. Medispec Model 3000 (SW-6) Extracorporeal Shockwave Lithotripsy System] – that will be utilized by appropriately trained health care professionals to treat patients who seek medical care for kidney stones. The proposed equipment has been approved for clinical use by the FDA.

See Attachment B.II.E.2: FDA Approval

See Attachment B.II.E.2: Picture of Mobile Lithotripsy Equipment

- a. List all sites that will be served;

The vendor-owned mobile lithotripsy equipment to be used for this project will serve the only two hospitals in Hamblen County:

- Morristown-Hamblen Hospital
- Lakeway Hospital

*Note: Morristown-Hamblen Hospital and Lakeway Hospital are in very close proximity to one another (i.e. approximately 100 feet of road and easement separate the two hospital campuses)*

- b. Provide current and/or proposed schedule of operations;

The anticipated initial schedule of operations for the MHH mobile lithotripsy service will be as follows:

- Tuesdays, Noon-5:00 PM
- Fridays, Noon-5:00 PM

Within the actual number of days approved by the HSDA for mobile lithotripsy operations, additional hours or alternative scheduling times are possible if needed to accommodate patient and/or physician needs.

- c. Provide the lease or contract cost.

The estimated contract cost for the initial term of the “per click” mobile lithotripsy equipment lease will be \$ \$315,900 – which represents a total cost of \$ 1,350 per procedure (i.e. “per click”) for 234 procedures anticipated for the initial equipment vendor contract

**term of 36 months** (please note: this sum of lease payments for the initial contract term is greater than the documented \$ 245,000 Fair Market Value of the equipment to be used for the project).

- d. Provide the fair market value of the equipment; and

**The estimated fair market value of the mobile lithotripsy equipment to be used for the project is \$ 245,000.**

**See Attachment B.II.E.2.d: Equipment FMV Letter**

- e. List the owner for the equipment.

**The mobile lithotripsy equipment to be leased and utilized by MHH for the proposed project is owned by Medispec LTD (i.e. Medispec LTD; 203 Perry Parkway, Suite 6; Gaithersburg, MD 20877; 888-663-3477).**

3. Indicate applicant's legal interest in equipment (i.e., purchase, lease, etc.) In the case of equipment purchase include a quote and/or proposal from an equipment vendor, or in the case of an equipment lease provide a draft lease or contract that at least includes the term of the lease and the anticipated lease payments.

**The mobile lithotripsy equipment will be leased from an established equipment vendor in the region (Medispec LTD) on a "per procedure" (or "per click") basis.**

**See Attachment B.II.E.3: Equipment Lease Proposal**

- III. (A) Attach a copy of the plot plan of the site on an 8 1/2" x 11" sheet of white paper which **must** include:

1. Size of site (*in acres*);
2. Location of structure on the site; and
3. Location of the proposed construction.
4. Names of streets, roads or highway that cross or border the site.

**See Attachment B.III.A: Plot Plan of the Site**

**Please note that the drawings do not need to be drawn to scale. Plot plans are required for all projects.**

- (B) 1. Describe the relationship of the site to public transportation routes, if any, and to any highway or major road developments in the area. Describe the accessibility of the proposed site to patients/clients.

The mobile lithotripsy equipment for the proposed project will be operated in Morristown, Tennessee at the well-known and accessible campus of Morristown-Hamblen Hospital (MHH) – which is located near downtown Morristown, in close proximity to State Highways 11E and 25E, and within 7 miles of Interstate 81. The proposed lithotripsy procedures will occur within the existing MHH surgery suite (Operating Room # 5), which is adjacent to adequate patient parking and convenient drop-off locations. The site is in close proximity to public transportation routes and accessible to patients arriving via public transportation services such as ETHRA (East Tennessee Human Resource Agency van services) and local cab companies which service Hamblen and surrounding counties. Additionally, MHH is 4.5 miles from the Morristown Airport and about 1 mile from a Greyhound bus terminal.

- IV. Attach a floor plan drawing for the facility which includes legible labeling of patient care rooms (noting private or semi-private), ancillary areas, equipment areas, etc. on an 8 1/2" x 11" sheet of white paper.

NOTE: **DO NOT SUBMIT BLUEPRINTS**. Simple line drawings should be submitted and need not be drawn to scale.

**See Attachment B.IV: Floor Plan**

- V. For a Home Health Agency or Hospice, identify:

**Not applicable.**

1. Existing service area by County;
2. Proposed service area by County;
3. A parent or primary service provider;
4. Existing branches; and
5. Proposed branches.

**SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED**

In accordance with Tennessee Code Annotated § 68-11-1609(b), "no Certificate of Need shall be granted unless the action proposed in the application for such Certificate is necessary to provide needed health care in the area to be served, can be economically accomplished and maintained, and will contribute to the orderly development of health care." The three (3) criteria are further defined in Agency Rule 0720-4-.01. Further standards for guidance are provided in the state health plan (Guidelines for Growth), developed pursuant to Tennessee Code Annotated §68-11-1625.

The following questions are listed according to the three (3) criteria: (I) Need, (II) Economic Feasibility, and (III) Contribution to the Orderly Development of Health Care. Please respond to each question and provide underlying assumptions, data sources, and methodologies when appropriate. Please type each question and its response on an 8 1/2" x 11" white paper. All exhibits and tables must be attached to the end of the application in correct sequence identifying the question(s) to which they refer. If a question does not apply to your project, indicate "Not Applicable (NA)."

**QUESTIONS****NEED**

1. Describe the relationship of this proposal toward the implementation of the State Health Plan and Tennessee's Health: Guidelines for Growth.

The proposed project seeks to initiate mobile lithotripsy services for MHH patients and physicians by utilizing an existing modern mobile lithotripsy unit that currently exists and operates within the region – and that has significant and sufficient open capacity available to support the needed project. This optimal approach to improving access to high quality healthcare services is orderly, efficient, and beneficial for key stakeholders in the region.

The proposed project is needed to improve access to lithotripsy services for patients and physicians within the project service area, reduce unnecessary patient burdens (i.e. time, suffering, and travel expense) related to lithotripsy case outmigration, and to help MHH better coordinate needed patient care services locally in an optimal and orderly manner. The project will improve lithotripsy accessibility, use, and benefit within the region by initiating lithotripsy services at the well-known MHH campus.

As outlined throughout this application, the proposed project supports the major tenets of the State Health Plan – including the promotion and support of "Healthy Lives" for specific patient populations; improving "Access to Care" in the service area for all residents; developing healthcare services in a manner to optimize "Economic Efficiencies"; ensuring high "Quality of Care" that is effective, patient-centered, timely, efficient, and equitable; and strengthening the "Healthcare Workforce" in the region in an effective and efficient manner.

- a. Please provide a response to each criterion and standard in Certificate of Need Categories that are applicable to the proposed project. Do not provide responses to General Criteria and Standards (pages 6-9) here.



STATE OF TENNESSEE  
**STATE HEALTH PLAN**  
CERTIFICATE OF NEED STANDARDS AND CRITERIA

*FOR*

**EXTRA-CORPOREAL SHOCK WAVE  
LITHOTRIPSY SERVICES**

The Health Services and Development Agency (HSDA) may consider the following standards and criteria for applications seeking to provide extra-corporeal shock wave lithotripsy (ESWL) services. Rationale statements for each standard are provided in an appendix. Existing providers of ESWL services are not affected by these standards and criteria unless they take an action that requires a new certificate of need (CON) for such services.

These proposed standards and criteria will become effective immediately upon approval and adoption by the governor. However, applications to provide ESWL services that are deemed complete by the HSDA prior to the approval and adoption of these standards and criteria shall be considered under the Guidelines for Growth, 2000 Edition.

**Definitions**

**Lithotripsy:** Lithotripsy is defined as the pulverization of urinary stones by means of a lithotripter. Extracorporeal lithotripsy is lithotripsy that occurs outside the body. Extracorporeal shock wave lithotripsy is the non-invasive procedure that uses shock waves to pulverize urinary stones, which can then be expelled in the urine. An emitter is placed in contact with the patient relative to where the stone is located and the shock waves are focused on the stone, which is shattered by the force.

**Procedure:** A "procedure" is the single provision of ESWL services as reported by its ICD9 code or the ESWL services facility's internal financial code that corresponds to the ESWL services CPT code.

**Service Area:** Refers to the county or counties represented by an applicant for ESWL services as the reasonable area to which the applicant intends to provide ESWL services and/or in which the majority of its current service recipients reside.

### Standards and Criteria

1. **Determination of Need:** The need for ESWL services is determined by applying the following formula:

$$N = (U \times P) + O$$

N = number of ESWL services procedures needed in a Service Area;

U = latest available Tennessee use rate (number of procedures performed per 1,000 population in the state as determined by the Tennessee Department of Health);

P = projection of population (in thousands) in the service area as determined by the Tennessee Department of Health for Tennessee counties and the United States Census Bureau for non-Tennessee counties; and

O = the number of out-of-state resident procedures performed within the applicant's Service Area in the same time frame used to determine U based upon publically reported data. The applicant should document the methodology used to count volume in out-of-state resident procedures and, if different from the definition of "procedure" described in these standards and criteria, should distinguish out-of-state procedures from in-state cases.

The need shall be based upon the Service Area's current year's population projected three years forward.

### Project Service Area

The "primary service area" for this lithotripsy project is Hamblen County from a traditional planning standpoint. As outlined within the Service Area section of this application (Section C.3), most of MHH's inpatients, outpatients, and emergency department patients reside in Hamblen County. Additionally, MHH and supporting physicians anticipate serving patients from other nearby counties and rural areas in the region where some MHH patients have resided historically (i.e. "secondary service area"). Therefore, the "Project Service Area" from a CON perspective includes Hamblen, Claiborne, Grainger, Jefferson, and Cocke Counties in East Tennessee.

The proposed mobile lithotripsy unit will enhance convenience, access, and technology for MHH patients living and working within the project service area that is marked by a growing and aging population – and relatively high levels of TennCare enrollment and poverty.



**Determination of Need****See Attachment C.1.a.1: TDH Lithotripsy Need Projections by County**

$$N = (U \times P) + O$$

**N = number of ESWL services procedures needed in a Service Area;**

As outlined in the attachment referenced above (*Extra-Corporeal Shock Wave Lithotripsy Need Projections By County and State Total, 2013 Data, Projected to 2017 – provided by the Tennessee Department of Health, Division of Policy, Planning, and Assessment, Office of Health Statistics in August 2014*), here are the projected number of procedures needed in the project's proposed service area for 2017:

<b>County</b>	<b>Projected Lithotripsy Need: 2017</b>
<b>Hamblen (Primary Service Area)</b>	<b>90</b>
<b>Grainger (Secondary Service Area)</b>	<b>32</b>
<b>Claiborne (Secondary Service Area)</b>	<b>46</b>
<b>Jefferson (Secondary Service Area)</b>	<b>77</b>
<b>Cocke (Secondary Service Area)</b>	<b>53</b>
<b>Others (Tertiary Service Area)</b>	<b>(N/A)</b>
<b>Total: CON Project Service Area</b>	<b>298</b>

**U = latest available Tennessee use rate (number of procedures performed per 1,000 population in the state as determined by the Tennessee Department of Health);**

As outlined in the attachment referenced above (*Extra-Corporeal Shock Wave Lithotripsy Need Projections By County and State Total, 2013 Data, Projected to 2017 – provided by the Tennessee Department of Health, Division of Policy, Planning, and Assessment, Office of Health Statistics in August 2014*), the current estimated "State Utilization Rate" for lithotripsy services is "0.0013781".

**P = projection of population (in thousands) in the service area as determined by the Tennessee Department of Health for Tennessee counties and the United States Census Bureau for non-Tennessee counties; and**

As outlined in the attachment referenced above (*Extra-Corporeal Shock Wave Lithotripsy Need Projections By County and State Total, 2013 Data, Projected to 2017 – provided by the Tennessee Department of Health, Division of Policy, Planning, and Assessment, Office of Health Statistics in August 2014*), provided below are the 2017 population projections for the project's proposed service area:

County	Projected Population: 2017
<b>Hamblen</b> ( <i>Primary Service Area</i> )	<b>65,181</b>
Grainger ( <i>Secondary Service Area</i> )	23,513
Claiborne ( <i>Secondary Service Area</i> )	33,110
Jefferson ( <i>Secondary Service Area</i> )	56,054
Cocke ( <i>Secondary Service Area</i> )	38,143
Others ( <i>Tertiary Service Area</i> )	(N/A)
<b>Total: CON Project Service Area</b>	<b>216,001</b>

**O** = the number of out-of-state resident procedures performed within the applicant's Service Area in the same time frame used to determine **U** based upon publically reported data. The applicant should document the methodology used to count volume in out-of-state resident procedures and, if different from the definition of "procedure" described in these standards and criteria, should distinguish out-of-state procedures from in-state cases.

The applicant expects that less than 1% of its total number of lithotripsy patients will be "out-of-state" residents for Years 1-3 of the project. While it is a possibility that a few out-of-state patients could be treated by the proposed MHH lithotripsy service each year, such patients have not been included in the utilization projections for the project.

The need shall be based upon the Service Area's current year's population projected three years forward.

Calculation for *Primary Service Area (PSA): Hamblen County*

$$N = (U \times P) + O$$

$$90 = (0.0013781 \times 65,181) + 0$$

Calculation for the *Total CON Project Service Area (PSA + SSA):*

$$N = (U \times P) + O$$

$$298 = (.0013781 \times 216,001) + 0$$

The estimated need for lithotripsy procedures in both Hamblen County and the Total CON Project Service Area will continue to increase as the total population in the MHH region grows and ages.

- **Minimum Volume Standard:** Applicants proposing to acquire and operate an ESWL services unit must project a minimum utilization of at least 250 procedures per year by the third year of operation, based on full-time use of an ESWL unit. The applicant must also document and provide data supporting the methodology used to project the patient utilization. An application to provide ESWL services on a part-time basis shall convert its projected use to that of a full-time equivalent ESWL unit.

MHH projects ESWL unit utilization to exceed the minimum volume standard “by the third year of operation”. In fact, based upon the request to operate lithotripsy services only part-time (i.e. two days per week) rather than full-time (i.e. seven days per week), MHH projects ESWL unit utilization to exceed the prorated minimum volume standard in both Year Two and Year Three of its ESWL operations.

Based upon assumptions that are both reasonable and conservative, projected annual ESWL utilization for the first three years of operations is summarized in the chart below:

	Year One (2015)	Year Two (2016)	Year Three (2017)
<b>ESWL Procedures</b>	<b>52</b>	<b>78</b>	<b>104</b>
<b>ESWL Procedures per Week</b>	<b>1.0 x 52 weeks</b>	<b>1.5 x 52 weeks</b>	<b>2.0 x 52 weeks</b>

These annual projections reflect demand currently observed by MHH physicians and staff, representing patients who are either sent to other East Tennessee providers of ESWL services – or who receive alternative care options although eligible for lithotripsy procedures. During much of the past year, MHH and its affiliated physicians have referred at least 1-2 kidney stone patients per week, and at times more (3-4 per week), to other providers in East Tennessee to receive needed lithotripsy procedures. MHH lithotripsy patients will be from the project service area as described elsewhere within this CON application.

Even if the hospital and its medical staff experience virtually no growth in patient demand for lithotripsy services during the next three years, recent levels of demand support the project’s conservative utilization projections that exceed the “Minimum Volume Standards” outlined Tennessee’s current State Health Plan.

- Full-time ESWL: 250 procedures per year / 52 Weeks per year = 4.8 procedures per week
- Converted to part-time ESWL: (2 days per week / 7 days per week) = .286 conversion factor
- Therefore: .286 x 4.8 procedures per week = 1.37 procedures per week

The chart below shows how the proposed ESWL utilization will exceed 1.37 procedures per week for each of the first three years of operations:

	Year One (2015)	Year Two (2016)	Year Three (2017)
<b>ESWL Procedures</b>	<b>52</b>	<b>78</b>	<b>104</b>
<b>ESWL Procedures per Week</b>	<b>1.0 x 52 weeks</b>	<b>1.5 x 52 weeks</b>	<b>2.0 x 52 weeks</b>

To further clarify how the project will exceed the minimum utilization guideline of “at least 250 procedures per year” for both Year Two and Year Three of the project, a simple conversion of MHH’s projected annual use to a “full time equivalent ESWL unit” for the first three years of operations is summarized in the chart below:

	Year One (2015)	Year Two (2016)	Year Three (2017)
<b>Conversion* of projected annual use to a “full time equivalent ESWL unit”</b>	<b>52 x “3.5” = 182</b> <i>(i.e. 182 &lt; 250)</i>	<b>78 x “3.5” = 273</b> <i>(i.e. 273 &gt; 250)</i>	<b>104 x “3.5” = 364</b> <i>(i.e. 364 &gt; 250)</i>

\* “Projected annual use for 2 days/week” x 3.5 = “?”

- **Current Service Area Utilization:** The applicant should document that all existing providers of ESWL services within the proposed Service Area each performed at least 300 ESWL procedures per year during the most recent 12 month period for which data are available. The utilization by ESWL units that operate on a part-time basis shall be converted to that of a full-time equivalent ESWL unit. To characterize existing providers located within Tennessee, the applicant should use data provided by the Health Services and Development Agency. To characterize providers located outside of Tennessee, the applicant should use publicly available data, if available, and describe in its application the methodology these providers use to count volume.

The only provider offering ESWL services in the CON project service area is Lakeway Hospital (CHS) in Hamblen County – which has been approved to perform mobile lithotripsy services “7 days per week” since 1997 (CN# 9705-039). However, Lakeway Hospital has been operating far below the current standards and criteria for lithotripsy services – and only performed six (6) mobile lithotripsy procedures during the most recent reporting year per the most recent HSDA Equipment Registry Data available (August 2014) and the most recent Hospital Joint Annual Report available (2013).

See Attachment C.1.a.3: Service Area Lithotripsy Providers and Utilization

Several months prior to filing this CON application for mobile lithotripsy services, MHH leadership communicated its plans to Lakeway Hospital (CHS) leadership and sought confirmation that this proposed project would not create an adverse impact on the only approved provider of ESWL services in the Service Area. The CHS/Lakeway leadership team has provided written confirmation that they are not opposed to this needed MHH project that will be developed in an orderly and efficient manner.

**See Attachment C.1.a.3-4: Letter from Lakeway Hospital RE: MHH Lithotripsy Project**

In addition, the applicant should provide the HSDA with a report of patient destination for ESWL services based on the most recent 12 months of publicly reported data. This report should list all facilities that provided ESWL services to residents of the proposed Service Area and the number of ESWL procedures performed on residents of the Service Area for each facility. The Tennessee Department of Health will assist applicants in generating this report utilizing the HDDS.

The attached chart provides information from the HSDA Medical Equipment Registry regarding Tennessee ESWL providers who provided services for residents of the proposed project service area for the most recent 12 months of publicly reported data (*i.e. 2013 Data from HSDA on August 4, 2014*).

**See Attachment C.1.a.3: Service Area Lithotripsy Patient Destinations**

4. **Adverse Impact on Existing Providers:** An application for ESWL services should not be approved if the new program will cause the annual caseload of existing ESWL programs within the Service Area to drop below an average of 300 procedures. The utilization by ESWL units that operate on a part-time basis shall be converted to that of a full-time equivalent ESWL unit. The patient origin study conducted for Standard 2, an analysis of patient origin data collected for Standard 3, and the referral data documented for Standard 3 should be used to determine whether such an adverse impact on existing providers is likely to occur.

The proposed project will not “cause the annual caseload of existing ESWL programs within the Service Area to drop below an average of 300 procedures”.

The only provider offering ESWL services in the CON project service area is Lakeway Hospital (CHS) in Hamblen County – which has been approved to perform mobile lithotripsy services “7 days per week” since 1997 (CN# 9705-039). However, Lakeway Hospital has been operating far below the current standards and criteria for lithotripsy services – and only performed six (6) mobile lithotripsy procedures during the most recent reporting year (*i.e. most recent available HSDA Medical Equipment Registry Data and Tennessee Hospital Joint Annual Report, 2013*).

Several months prior to filing this CON application for mobile lithotripsy services, MHH leadership communicated its plans to Lakeway Hospital (CHS) leadership and sought confirmation that this proposed project would not create an adverse impact on the only approved provider of ESWL services in the Service Area. The CHS/Lakeway leadership team has provided written confirmation that they are not opposed to this needed MHH project that will be developed in an orderly and efficient manner.

**See Attachment C.1.a.3-4: Letter from Lakeway Hospital RE: MHH Lithotripsy Project**

- **Adequate Staffing and Services:** The applicant should document a plan for recruiting and maintaining a sufficient number of qualified professional and technical staff to provide the ESWL services and must document the following:
  - a. The existence of an active radiology service and an established referral urological practice;
  - b. The availability within 90 minutes' drive time of acute inpatient services for patients who experience complications; and
  - c. The fact that all individuals using the equipment meet the training and credentialing requirements of the American College of Surgeons' Advisory Council for Urology.

The applicant should also document an ongoing educational plan for all staff included in the ESWL services program.

MHH currently has sufficient professional and technical staff to support the proposed ESWL services, including Surgery Department leadership with experience performing ESWL procedures and/or managing operations of an ESWL service. Moreover, MHH will work with its medical staff and Medispec LTD (equipment manufacturer and vendor) to enhance its ongoing educational plan for all Surgery Department staff as appropriate – and to ensure that all staff involved with the proposed ESWL services program meet all recommended training requirements prior to treating patients.

- MHH is a long-established and credentialed hospital that has an active radiology service and an established referral urological practice.
- MHH is a long-established credentialed hospital that operates both acute inpatient care services and emergency care services that would be immediately accessible on site to any patient who might experience complications or who might need care for other reasons and conditions.
- MHH and its Medical Staff are prepared to meet and exceed the staffing recommendations and requirements set forth by the American College of Surgeons' Advisory Council for Urology and by Medispec LTD, including all recommended staff education requirements, training, and certifications. The

proposed contract with Medispec LTD will cover appropriate training to help ensure safe and efficient patient care and equipment operations.

6. **ESWL Equipment:** Only applications that provide for the provision of ESWL services using equipment that has been approved by the United States Food and Drug Administration for clinical use shall be approvable.

The proposed mobile lithotripsy equipment has been approved for use by the FDA.

See Attachment C.1.a.6: FDA Approval

7. **Quality Control and Monitoring:** The applicant should identify and document its intention to participate in a data reporting, quality improvement, outcome monitoring, and peer review system that benchmarks outcomes based on national norms. The system should provide for peer review among professionals practicing in facilities and programs other than the applicant.

MHH will continue to support the State of Tennessee's goals and principles for *"achieving better health"* through ongoing accountability, public data reporting, peer review, outcomes monitoring, and other patient care quality assurances so that it's patients will *"have confidence that the quality of health care is continually monitored and standards are adhered to..."* in a manner consistent to the State Health Plan.

The MHH ESWL service will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements. Moreover, qualified employees of the MHH Surgery Department will manage routine ESWL procedures and any emergency procedures or related issues in conformity with accepted medical practice. If the CON project is approved, MHH will develop and implement appropriate Policies and Procedures for ESWL services.

All ESWL procedures will be performed in accordance with appropriate clinical protocols and initiated under the direction of appropriately certified or licensed medical personnel. MHH will establish and/or follow appropriate ESWL guidelines in conjunction with the established lithotripsy operations of other Covenant Health affiliates.

Board certified urologists and/or other appropriately licensed physicians with appropriate training and certifications will provide overall patient care supervision to ensure that applicable clinical performance standards are met for all ESWL procedures.

As outlined elsewhere within this CON application, MHH meets the licensing and accreditation requirements of the State of Tennessee, The Joint Commission, CMS, and others.

8. **Data Requirements:** Applicants should agree to provide the Department of Health and/or the HSDA with all reasonably requested information and statistical data related to the operation and provision of services and to report that data in the time and format requested. As a standard of practice, existing data reporting streams will be relied upon and adapted over time to collect all needed information.

If requested by the Tennessee Department of Health, the Tennessee Health Services and Development Agency, and/or other State agencies, MHH will provide accurate and appropriate statistics regarding its proposed ESWL service and other data as required.

9. **Transfer and/or Affiliation Agreements:** If an applicant is not a designated Level 1 trauma center, an applicant must document an acceptable plan for the development of transfer and/or affiliation agreements with hospitals in the service area (this criterion does not preclude the development of transfer agreements with facilities outside the applicant's Service Area).

MHH is a community hospital offering many services, both at the main hospital campus and at a few satellite sites. As a community hospital, MHH has considerable experience managing and maintaining patient transfer agreements with other providers – both within the project service area and beyond.

See Attachment C.1.a.9: MHH Transfer Agreements

The proposed ESWL service will be operated as an integral part of the MHH Surgical Department and in close proximity to the hospital's Emergency Department, acute care units, and key outpatient service settings. The ESWL service will be provided in a setting supported by physicians and clinical personnel who will be prepared to provide any needed emergency care immediately – and/or make appropriate transfers to other qualified and trained clinical professionals through close relationships with area EMS providers and other hospitals in East Tennessee. The main MHH campus provides continual access to credentialed medical professionals and trained clinical staff prepared to handle emergency transfers.

10. **Access:** In addition to the factors set forth in HSDA Rule 0720-11-.01 (1) (listing the factors concerning need on which an application may be evaluated), the HSDA may choose to give special consideration to an applicant:

- a. That is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;

**Not Applicable.**

- b. That documents that the service area population experiences a prevalence and/or incidence of urinary stones or other clinical conditions applicable to extra-corporeal shock wave lithotripsy services that is substantially higher than the State of Tennessee average; or



The applicant contends that the service area population may experience a higher prevalence and/or incidence of urinary stones than might be indicated by the current state average and projected utilization rates.

For instance, as outlined in other sections of this CON application and related attachments, the current Tennessee Department of Health ESWL need projections for the project service area anticipate that residents of the region will only need 298 ESWL procedures in 2017. However, the most recent update of the HSDA Medical Equipment Registry documents that residents of the service area needed at least 293 procedures in 2013. As the population of the Service Area grows and ages, it is reasonable to expect ESWL demand to increase by significantly more than only 5 procedures.

Moreover, in recent years, the MHH medical staff has witnessed approximately 300 annual patient encounters related to kidney stones in the hospital's emergency department, as well as others within physician office settings. While not all of these patients are candidates for lithotripsy procedures, significant and growing demand for lithotripsy procedures at MHH has been confirmed by local physicians (*please see Attachment B.1.a. Physician Support Letters*). Realistically and conservatively, up to 50% or more of these actual patients could be clinically appropriate candidates for lithotripsy procedures.

Both data review and actual clinical observation by local healthcare professionals indicate that the real need for lithotripsy services in the region may exceed the current demand estimates available from the Tennessee Department of Health. To address such anticipated demand, the proposed project will improve access to an important clinical service in the region and seek to reduce burdens for many patients. The proposed project will serve any and all patients needing lithotripsy procedures within the region.

- c. That is a "safety net hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program.

Although not classified as a "safety net hospital", MHH is an important component of the TennCare provider network within the hospital's service area. MHH has a proven history of serving TennCare, Medicare, and uninsured patients as a not-for-profit community hospital that offers many important clinical services that have been historically under-funded.

Like all the other hospital-based services of MHH, this project will be accessible to all patients in the region since MHH is a contracted provider with all area TennCare MCOs and has a long history of serving all patients regardless of race, ethnicity, gender, age, or income level.

- b. Applications that include a Change of Site for a health care institution, provide a response to General Criterion and Standards (4)(a-c)

Not applicable.

2. Describe the relationship of this project to the applicant facility's long-range development plans, if any.

**As part of its long-range facility planning efforts, Morristown-Hamblen Hospital (MHH) regularly evaluates evolving community needs for inpatient, outpatient, emergency, and physician office services in the region. This current project represents an orderly and timely continuation of MHH plans to maintain high quality and accessible services needed within the project service area – and to improve care access for MHH inpatients, outpatients, and emergency room patients.**

**The primary goal of the proposed project is to improve access to ESWL services for both patients and physicians in the project service area by initiating the mobile service at MHH in an orderly and efficient manner. Consistent with the community-oriented mission of MHH, the hospital seeks to strengthen its historical commitment and recognized value as a leading provider of high quality patient care for the people who reside within region. The proposed project promotes this important planning goal by assuring continued and improved access to this needed clinical technology for all patients in the region. The proposed ESWL service will allow MHH to reduce patient burdens while improving operational efficiencies, patient and physician satisfaction, and overall continuum of care coordination.**

**As part of its long range development plans, MHH seeks to initiate ESWL services on a part-time basis (only two days per week) to meet the anticipated needs of its patients and medical staff for the foreseeable future (i.e. next 3-5 years). If additional capacity is ever needed in the future, MHH leadership and the hospital's medical staff will discuss such perceived needs with the mobile lithotripsy equipment vendor, other providers in the region, and the Tennessee Health Services and Development Agency as appropriate.**

3. Identify the proposed service area and justify the reasonableness of that proposed area. Submit a county level map including the State of Tennessee clearly marked to reflect the service area. Please submit the map on 8 1/2" x 11" sheet of white paper marked only with ink detectable by a standard photocopier (i.e., no highlighters, pencils, etc.).

While MHH serves patients from a broad geographic region within East Tennessee (and occasional patients from elsewhere), the "primary service area" for this lithotripsy project is Hamblen County from a traditional planning standpoint. As outlined in the charts below, most of MHH's inpatients, outpatients, and emergency department patients reside in Hamblen County. Additionally, MHH and supporting physicians anticipate serving patients from other nearby counties and rural areas in the region where some MHH patients have resided historically (i.e. "secondary service area"). Therefore, the "Project Service Area" from a CON perspective includes Hamblen, Claiborne, Grainger, Jefferson, and Cocke Counties in East Tennessee.

The proposed mobile lithotripsy unit will enhance convenience, access, and technology for MHH patients living and working within the project service area that is marked by a growing and aging population – and relatively high levels of TennCare enrollment and poverty.

**See Attachment C.3. – Service Area Map**

The proposed service area for this mobile lithotripsy project is reasonable since the geography is consistent with counties of patient origin for MHH: 1) Inpatients; 2) Outpatients; and 3) Emergency Department Patients. Additionally, the proposed service area is consistent with the counties of patient origin for key physicians who will refer to the proposed mobile lithotripsy unit – and for the key urologist who will perform many of the proposed mobile lithotripsy procedures at MHH.

In 2013, MHH received most of its Inpatients from Hamblen County:

**MHH – 2013 Inpatients (IP) by County**

County	Inpatients*	% of Total	Cumulative %
<b>Hamblen (PSA)</b>	<b>3,800</b>	<b>57.6%</b>	<b>57.6%</b>
Grainger	661	10.0%	67.6%
Jefferson	647	9.8%	77.4%
Cocke	575	8.7%	86.1%
Claiborne	98	1.5%	87.6%
<i>All Others (TN + Outside)</i>	813	12.4%	100.0%
<b>Total</b>	<b>6,594</b>	<b>100%</b>	<b>100%</b>

\* Excludes Newborns and Behavioral Health

Source: Internal Records – MHH

In 2013, MHH received most of its Outpatients from Hamblen County:

**MHH – 2013 Outpatients (OP) by County**

County	Outpatients*	% of Total	Cumulative %
<b>Hamblen (PSA)</b>	<b>45,549</b>	<b>60.1%</b>	<b>60.1%</b>
Jefferson	7,906	10.4%	70.5%
Grainger	7,175	9.5%	80.0%
Cocke	5,713	7.5%	87.5%
Claiborne	983	1.3%	88.8%
<i>All Others (TN + Outside)</i>	<i>8,450</i>	<i>11.2%</i>	<i>100.0%</i>
<b>Total</b>	<b>75,776</b>	<b>100%</b>	<b>100%</b>

\* Includes Emergency Department and Ambulatory Surgery Patients

Source: Internal Records – MHH

In 2013, MHH received most of its Emergency Department Patients from Hamblen County:

**MHH – 2013 Emergency Department (ED) Patients by County**

County	ED Patients*	% of Total	Cumulative %
<b>Hamblen (PSA)</b>	<b>20,244</b>	<b>66.9%</b>	<b>66.9%</b>
Grainger	2,869	9.5%	76.4%
Jefferson	2,442	8.1%	84.4%
Cocke	1,594	5.3%	89.7%
Claiborne	183	0.6%	90.3%
<i>All Others (TN + Outside)</i>	<i>2,936</i>	<i>9.7%</i>	<i>100.0%</i>
<b>Total</b>	<b>30,268</b>	<b>100%</b>	<b>100%</b>

Source: Internal Records – MHH

## 4.A. Describe the demographics of the population to be served by this proposal.

**Project Service Area: Total Population Projections**

	2013 Total Population	2014 Total Population	2015 Total Population	2016 Total Population	2017 Total Population
<b><u>Primary Service Area</u></b>					
<b>Hamblen</b>	63,763	64,108	64,438	64,799	65,181
<b><u>Secondary Service Area Counties</u></b>					
Jefferson	53,006	53,729	54,482	55,255	56,054
Cocke	36,330	36,762	37,207	37,652	38,143
Grainger	22,994	23,111	23,236	23,357	23,513
Claiborne	32,457	32,604	32,765	32,921	33,110
<b><u>Total CON Project Service Area:</u></b>	<b><u>208,550</u></b>	<b><u>210,314</u></b>	<b><u>212,128</u></b>	<b><u>213,984</u></b>	<b><u>216,001</u></b>
<b>State of TN</b>	6,528,014	6,588,698	6,649,438	6,710,579	6,772,022

Source: Tennessee Department of Health (TDH), Division of Health Statistics (6-2013 Revision)

Website: <http://health.state.tn.us/statistics/quickfacts.htm>

The Total Population estimate for Hamblen County in 2014 is 64,108, which is expected to increase to 65,181 by 2017 (1.67% increase vs. 2.78% for Tennessee). The expected Total Population growth for the *Total CON Project Service Area* (2.70% for 2014-2017) is similar to the estimated growth for Tennessee (2.78%).

**Project Service Area: Age 65+ Population Projections**

	2013 Total Population	2014 Total Population	2015 Total Population	2016 Total Population	2017 Total Population
<b><u>Primary Service Area</u></b>					
<b>Hamblen</b>	10,973	11,269	11,522	11,681	11,855
<b><u>Secondary Service Areas Counties</u></b>					
Jefferson	9,597	9,972	10,334	10,660	10,977
Cocke	6,548	6,669	6,762	6,796	6,848
Grainger	4,085	4,204	4,329	4,421	4,484
Claiborne	5,742	5,880	6,000	6,136	6,258
<b><u>Total CON Project Service Area:</u></b>	<b><u>36,945</u></b>	<b><u>37,994</u></b>	<b><u>38,947</u></b>	<b><u>39,694</u></b>	<b><u>40,422</u></b>
<b>State of TN</b>	950,177	981,984	1,012,937	1,042,071	1,072,143

Source: Tennessee Department of Health (TDH), Division of Health Statistics (6-2013 Revision)

Website: <http://health.state.tn.us/statistics/quickfacts.htm>

In 2014, 17.6% of the Hamblen County Total Population estimate is Age 65+ and 18.1% of the *Total CON Project Service Area* Population is Age 65+. Both estimates are significantly higher than the 14.9% Age 65+ estimate for Tennessee.

In 2017, both Hamblen County (18.2%) and the *Total CON Project Service Area* (18.7%) will have a higher estimated percentage of Age 65+ residents than Tennessee (15.8%).

4.B. Describe the special needs of the service area population, including health disparities, the accessibility to consumers, particularly the elderly, women, racial and ethnic minorities, and low-income groups. Document how the business plans of the facility will take into consideration the special needs of the service area population.

The proposed mobile lithotripsy unit will enhance convenience, access, and technology for MHH patients living and working within the project service area. The proposed project will serve the growing and aging population of Hamblen County, as well as some patients who reside in other nearby areas in the region that may seek care at MHH.

The project service area reflects considerable demographic and socioeconomic diversity. The planned project will improve access to ESWL technology used for many patients who need clinical care for kidney stones.

#### Elderly (Age 65+):

Maintaining and improving lithotripsy services in the region will be beneficial to the growing elderly population of the project service area.

Within both Hamblen County (PSA) and the Total CON Project Service Area, there is a greater percentage of individuals who are over 65 years of age when compared to the State of Tennessee as a whole:

- In 2014, 17.6% of the Hamblen County Total Population estimate is Age 65+ and 18.1% of the Total CON Project Service Area Population is Age 65+; both estimates are significantly higher than the current 14.9% Age 65+ estimate for Tennessee.
- In 2017, both Hamblen County (18.2%) and the Total CON Project Service Area (18.7%) will have a higher estimated percentage of Age 65+ residents than Tennessee (15.8%).

It is generally acknowledged that the incidence of many illnesses, medical conditions, and need for clinical services increases with increasing age. The benefits of this project should be realized significantly by the Age 65+ population in the service area. The mobile lithotripsy unit will be located at the convenient and well-known main hospital campus of MHH, which has adequate parking, support functions, and amenities to address elderly patient needs.

This project assumes that 57% of MHH lithotripsy patients during the first year of the project will be Medicare enrollees, which is consistent with historical utilization of many other MHH services.

#### Low-income Groups:

As indicated on the following chart, the median household income in Hamblen County (\$39,316) is less than the median household income for the State of Tennessee as a whole (\$44,140). There is a significant percentage of the Hamblen County population that is living below the poverty level (18.6% vs. 17.3% for Tennessee). Moreover, the following

chart also indicates that low median household incomes and higher percentages below the poverty level exist within other key geographies from which some MHH lithotripsy patients will originate.

	Median household income, 2008-2012	Persons below poverty level, percent, 2008-2012
<b>Primary Service Area</b>		
<b>Hamblen</b>	<b>\$39,316</b>	<b>18.60%</b>
<b>Secondary Service Area Counties</b>		
Jefferson	\$38,800	19.20%
Cocke	\$29,764	26.00%
Grainger	\$33,185	20.20%
Claiborne	\$33,568	23.00%
<b>State of TN</b>	<b>\$44,140</b>	<b>17.30%</b>

Source: U.S. Census Bureau – State and County Quick Facts (September 2014)

MHH is a not-for-profit community hospital that will continue to serve all patients regardless of race, ethnicity, gender, age, or income level.

#### TennCare Enrollees:

As indicated in the following chart, Hamblen County has a significantly higher percentage of its total population enrolled in TennCare than does Tennessee as a whole (21.1% for Hamblen County vs. 18.8% for Tennessee). The following chart also indicates relatively high percentages of TennCare enrollment for other key geographies near Hamblen County from which some MHH lithotripsy patients may originate.

	Female Total	Male Total	Grand Total	Percent Enrolled
<b>Primary Service Area</b>				
<b>Hamblen County</b>	<b>7,707</b>	<b>5,812</b>	<b>13,519</b>	<b>21.1%</b>
<b>Secondary Service Area Counties</b>				
Jefferson	6,013	4,555	10,568	19.7%
Cocke	5,745	4,439	10,184	27.7%
Grainger	2,855	2,263	5,118	22.1%
Claiborne	4,561	3,560	8,121	24.9%
<b>State of TN</b>	<b>716,799</b>	<b>524,228</b>	<b>1,241,028</b>	<b>18.8%</b>

Source: TennCare Bureau Website – TennCare Enrollment Data as of April 2014

MHH is a contracted provider in all TennCare plans in the region, so the service will be available to all TennCare enrollees to the extent approved by the TennCare MCOs.

This project assumes that 15% of the MHH lithotripsy patients during the first year of the project will be TennCare enrollees, which is consistent with the historical utilization of other services at MHH. It is anticipated that the total number of TennCare patients that utilize lithotripsy services at MHH may increase over time with improved access and convenience in the region.

#### Community Health Concerns:

The service area population may experience a higher prevalence and/or incidence of urinary stones than might be indicated by the current state average and projected utilization rates.

For instance, as outlined in other sections of this CON application and related attachments, the current Tennessee Department of Health ESWL need projections for the project service area anticipate that residents of the region will only need 298 ESWL procedures in 2017. However, the most recent update of the HSDA Medical Equipment Registry documents that residents of the service area needed at least 293 procedures in 2013. As the population of the Service Area grows and ages, it is reasonable to expect ESWL demand to increase by significantly more than only 5 procedures.

Moreover, in recent years, the MHH medical staff has witnessed approximately 300 annual patient encounters related to kidney stones in the hospital's emergency department, as well as others within physician office settings. While not all of these patients are candidates for lithotripsy procedures, significant and growing demand for lithotripsy procedures at MHH has been confirmed by local physicians (*please see Attachment B.I.a. Physician Support Letters*). Realistically and conservatively, up to 50% or more of these actual patients could be clinically appropriate candidates for lithotripsy procedures.

Both data review and actual clinical observation by local healthcare professionals indicate that the real need for lithotripsy services in the region may exceed the current demand estimates available from the Tennessee Department of Health. To address such anticipated demand, the proposed project will improve access to an important clinical service in the region and seek to reduce burdens for many patients. The proposed project will serve any and all patients needing lithotripsy procedures within the project service area.



5. Describe the existing or certified services, including approved but unimplemented CONs, of similar institutions in the service area. Include utilization and/or occupancy trends for each of the most recent three years of data available for this type of project. Be certain to list each institution and its utilization and/or occupancy individually. Inpatient bed projects must include the following data: admissions or discharges, patient days, and occupancy. Other projects should use the most appropriate measures, e.g., cases, procedures, visits, admissions, etc.

There are no “approved but unimplemented CONs” for ESWL services in the service area. According to the Health Services and Development Agency’s Medical Equipment Registry (*i.e. latest available data in August 2014 showing 2013 Data*), the only other approved provider of lithotripsy services in the project’s service area is Lakeway Hospital (owned and operated by CHS). However, although Lakeway Hospital has been approval to operate mobile lithotripsy equipment seven days a week, Lakeway only performed six (6) total procedures during most recent reporting year available via the HSDA Medical Equipment Registry (2013) – and only six (6) total lithotripsy procedures are reported on the 2013 Hospital Joint Annual Report for Lakeway Hospital (<http://health.state.tn.us/PublicJARS/Reports/hospital/Current/32252.pdf>).

See Attachment C.5.

Health Care Providers that Operate Lithotripsy Equipment in Project Service Area

Prior to the filing of this CON application, the CHS/Lakeway leadership team provided written confirmation that they are not opposed to this needed MHH project that will be developed in an orderly manner (*i.e. see Attachment B.I.b: Letter from CHS/Lakeway Hospital*).

6. Provide applicable utilization and/or occupancy statistics for your institution for each of the past three (3) years and the projected annual utilization for each of the two (2) years following completion of the project. Additionally, provide the details regarding the methodology used to project utilization. The methodology must include detailed calculations or documentation from referral sources, and identification of all assumptions.

There are no historical utilization statistics for lithotripsy services at MHH since this CON application seeks approval to initiate lithotripsy services and operate a vendor-owned mobile lithotripsy device that currently exists in the service area.

The projected annual utilization for each of the first three years following completion of the project is summarized in the chart below:

Projected Annual Utilization for Year 1, Year 2, and Year 3:

<u>Projected Annual Utilization</u>	<u>Year 1: 2015</u>	<u>Year 2: 2016</u>	<u>Year 3: 2017</u>
Mobile Lithotripsy Procedures	52	78	104

Projected utilization methodology calculations, assumptions, and justifications for this proposed project are summarized below:

County of Patient Origin	Approximate % of Total Cases	Year One (2015)	Year Two (2016)	Year Three (2017)
Hamblen (PSA)	58 %	30	45	60
Grainger (SSA)	15.5 %	8	12	16
Claiborne* (SSA)	15.5 %	8	12	16
Jefferson (SSA)	6 %	3	5	6
Cocke (SSA)	2 %	1	2	2
Other TN Counties** (TSA)	3 %	2	2	4
Out of State*** (TSA)	0 %	0	0	0
<b>Total****</b>	<b>100.0%</b>	<b>52</b>	<b>78</b>	<b>104</b>

**Notes:**

- **PSA = Primary Service Area; SSA = Secondary Service Area; TSA = Tertiary Service Area**
- **County of Patient Origin:** please see both service area descriptions and justifications in Sections C.3 and C.4 for background information regarding anticipated geographies of patient origin that are reasonable for this project. The projected utilization anticipated from each county of the project service area is significantly below the State's projected ESWL need levels anticipated for the next three years.
- **Claiborne\* County:** based upon recent experience by healthcare providers in Claiborne County\*, the Claiborne Medical Center (CMC) leadership team has confirmed that it anticipates sending at least one or two patients each month to MHH if the ESWL service is approved so patient access in the service area can be expanded. MHH is most easily accessible to many Claiborne County residents via State Highway 25 E, as well as via other travel routes. Both MHH and CMC are clinically aligned affiliates of Covenant Health.
- **Other Tennessee (TN) Counties\*\*** from which MHH may draw a very few lithotripsy patients (i.e. up to 3% collectively; representing only 2-3 patients combined annually for years 1-3 of the project) include the following: Anderson, Sevier, Knox, Union, Campbell, Hancock, Hawkins, Greene, Washington, Sullivan, and others.
- **Out of State\*\*\*** the applicant expects that less than 1% of its total number of lithotripsy patients will be "out-of-state" residents for Years 1-3 of the project. While it is a possibility that a few out-of-state patients could be treated by the proposed MHH lithotripsy service each year, such patients have not been included in the utilization projections for the project.
- **Total\*\*\*\*** projected ESWL utilization for the project is considered reasonable and conservative considering projected need and population estimates from the Tennessee Department of Health; documented outmigration from the service area to seek care in recent years; the significant and increasing number of kidney stone patients observed by providers in Hamblen county; and due to the fact that anticipated ESWL procedure volumes for each of years 1-3 of the proposed MHH project are significantly less than the total number of ESWL procedures performed at other Covenant Health hospitals (outside the service area) for patients who reside within the project service area (i.e. as summarized in Attachment C.1.a.3, which shows 120 combined procedures in 2013 from the MHH lithotripsy project service area that were performed and reported by Fort Sanders Regional Medical Center, Parkwest Medical Center, Methodist Medical Center, and LeConte Medical Center). Moreover, strong physician support for this project, demographic considerations in the region that should increase demand over time, and the anticipation of both increased patient access and general community awareness about the benefits of ESWL services if the project is approved further support the utilization projections for this CON application.

**ECONOMIC FEASIBILITY**

2. Provide the cost of the project by completing the Project Costs Chart on the following page. Justify the cost of the project.

- All projects should have a project cost of at least \$3,000 on Line F. (Minimum CON Filing Fee). CON filing fee should be calculated from Line D. (See Application Instructions for Filing Fee)
- The cost of any lease (building, land, and/or equipment) should be based on fair market value or the total amount of the lease payments over the initial term of the lease, whichever is greater. Note: This applies to all equipment leases including by procedure or "per click" arrangements. The methodology used to determine the total lease cost for a "per click" arrangement must include, at a minimum, the projected procedures, the "per click" rate and the term of the lease.
- The cost for fixed and moveable equipment includes, but is not necessarily limited to, maintenance agreements covering the expected useful life of the equipment; federal, state, and local taxes and other government assessments; and installation charges, excluding capital expenditures for physical plant renovation or in-wall shielding, which should be included under construction costs or incorporated in a facility lease.
- For projects that include new construction, modification, and/or renovation; documentation must be provided from a contractor and/or architect that support the estimated construction costs.

**REPLACEMENT PAGE 38**

**PROJECT COSTS CHART**

<b>A. Construction and equipment acquired by purchase:</b>		
1.	Architectural and Engineering Fees	
2.	Legal, Administrative (Excluding CON Filing Fee), Consultant Fees	5,000
3.	Acquisition of Site	0
4.	Preparation of Site	0
5.	Construction Costs	0
6.	Contingency Fund	5,000
7.	Fixed Equipment (Not included in Construction Contract)	0
* 8.	Moveable Equipment (List all equipment over \$50,000)	0
9.	Other (Specify) _____	0
<b>B. Acquisition by gift, donation, or lease:</b>		
1.	Facility (inclusive of building and land)	0
2.	Building only	0
3.	Land only	0
4.	Equipment ( <b>Mobile Lithotripsy Equipment Lease*</b> )	315,900
5.	Other (Specify) _____	0
<b>C. Financing Costs and Fees:</b>		
1.	Interim Financing	0
2.	Underwriting Costs	0
3.	Reserve for One Year's Debt Service	0
4.	Other (Specify) _____	0
D.	Estimated Project Cost (A+B+C)	325,900
E.	CON Filing Fee	3,000
F.	Total Estimated Project Cost (D+E)	
	<b>TOTAL</b>	<b>328,900</b>

\* **Note:** The mobile lithotripsy unit to be leased from a vendor is the only medical equipment item over \$50,000 needed for the project (line A.8 of the Project Costs Chart):

Moveable Equipment over \$50,000	Cost**
Mobile Lithotripsy Device: <i>MEDISPEC Econolith E3000, Model 3000 (SW-6)</i>	\$ 315,900

\*\* The estimated contract cost for the initial term of the mobile lithotripsy equipment lease will be \$ \$315,900 – which represents a total cost of \$ 1,350 per procedure (i.e. “per click”) for 234 procedures anticipated for the initial equipment vendor contract term of 36 months (Y1: 52 + Y2: 78 + Y3: 104 = 234 Total Procedures for Y1-Y3).

See Attachment C, Economic Feasibility, 1 – Preliminary Equipment Lease Quote

This total anticipated sum of lease payments for the initial contract term is greater than the documented Fair Market Value of the equipment to be used for the project (\$ 245,000).

See Attachment C, Economic Feasibility, 1 – Equipment FMV Documentation

2. Identify the funding sources for this project.

Please check the applicable item(s) below and briefly summarize how the project will be financed. (Documentation for the type of funding *MUST* be inserted at the end of the application, in the correct alpha/numeric order and identified as Attachment C, Economic Feasibility-2.)

- ☐ A. Commercial loan--Letter from lending institution or guarantor stating favorable initial contact, proposed loan amount, expected interest rates, anticipated term of the loan, and any restrictions or conditions;
- ☐ B. Tax-exempt bonds--Copy of preliminary resolution or a letter from the issuing authority stating favorable initial contact and a conditional agreement from an underwriter or investment banker to proceed with the issuance;
- ☐ C. General obligation bonds—Copy of resolution from issuing authority or minutes from the appropriate meeting.
- ☐ D. Grants--Notification of intent form for grant application or notice of grant award; or
- ☒ E. Cash Reserves--Appropriate documentation from Chief Financial Officer.
- ☐ F. Other—Identify and document funding from all other sources.

Covenant Health, the parent company of Morristown-Hamblen Hospital, has sufficient cash reserves to complete the proposed project at the estimated total project cost of \$ 328,900 for certificate of need purposes. However, there is no required capital outlay by either MHH or Covenant Health for this project which simply creates operational access to a vendor-owned mobile lithotripsy unit via a “per procedure” (“per click”) equipment lease arrangement.

See Attachment C, Economic Feasibility, 2 – Documentation of Funding Type

3. Discuss and document the reasonableness of the proposed project costs. If applicable, compare the cost per square foot of construction to similar projects recently approved by the Health Services and Development Agency.

There is no required construction or renovation cost for this project since an existing operating room in the surgical department at MHH will be used for all lithotripsy procedures to be performed using the mobile equipment that will be moved into the suitable surgery suite when needed.

Therefore, the overall average cost per square foot of needed construction and/or renovations for this project is \$ 0.00 per square foot.

4. Complete Historical and Projected Data Charts on the following two pages – Do not modify the Charts provided or submit Chart substitutions! Historical Data Chart represents revenue and expense information for the last *three (3)* years for which complete data is available for the institution. Projected Data Chart requests information for the two (2) years following the completion of this proposal. Projected Data Chart should reflect revenue and expense projections for the *Proposal Only* (i.e., if the application is for additional beds, include anticipated revenue from the proposed beds only, not from all beds in the facility).

The following two pages contain: 1) the completed Historical Data Chart for Morristown-Hamblen Hospital and 2) the Projected Data Chart for the proposed mobile lithotripsy project.

5. Please identify the project's average gross charge, average deduction from operating revenue, and average net charge.

The project's average projected gross charge, average estimated deduction from operating revenue, and average projected net charge are presented below. No adjustments for inflation are assumed.

Average Projected “Gross Charge” = \$14,988  
Average Estimated “Deduction” = \$11,160  
Average Projected “Net Charge” = \$3,828

**HISTORICAL DATA CHART**

Give information for the last *three (3)* years for which complete data are available for the facility or agency. The fiscal year begins in **January**.  
**October 29, 2014**  
**10:28 am**

	Year 2011	Year 2012	Year 2013
A. Utilization Data (Adjusted Admissions)	15,164	15,189	14,657
B. Revenue from Services to Patients			
1 Inpatient Services	129,246,391	127,869,431	137,313,106
2 Outpatient Services	144,821,406	161,046,096	151,182,054
3 Emergency Services	17,366,623	17,685,638	17,302,302
4 Other Operating Revenue (Specify): <u>Cafeteria, Gift Shop, etc.</u>	2,275,139	2,340,721	2,795,001
<b>Gross Operating Revenue</b>	<b>293,709,559</b>	<b>308,941,886</b>	<b>308,592,462</b>
C. Deductions from Revenue			
1 Contractual Adjustments	179,403,258	193,915,995	198,813,844
2 Provision for Charity Care	14,161,394	12,707,142	12,564,453
3 Provisions for Bad Debt	15,688,309	18,531,240	12,122,619
<b>Total Deductions</b>	<b>209,252,961</b>	<b>225,154,377</b>	<b>223,500,916</b>
<b>NET OPERATING REVENUE</b>	<b>84,456,598</b>	<b>83,787,509</b>	<b>85,091,546</b>
D. Operating Expenses			
1 Salaries and Wages	34,202,053	30,774,732	29,043,945
2 Physician's Salaries and Wages	2,113,712	2,796,141	172,764
3 Supplies	22,468,530	21,556,295	21,941,369
4 Taxes	148,782	201,093	116,243
5 Depreciation	5,449,733	6,163,969	6,912,324
6 Rent	231,234	404,662	74,226
7 Interest, other than Capital	82,913	71,787	67,330
8 Management Fees:			
a. Fees to Affiliates	2,450,000	3,876,179	4,154,126
b. Fees to Non-Affiliates	-	-	-
9 Other Expenses (Specify):			
1. Benefits	6,122,737	6,467,888	5,081,545
2. Maintenance	2,612,335	2,317,557	2,048,630
3. Energy, Water & Telephones.	1,629,794	1,696,544	1,547,585
4. Professional Services & Insurance	7,653,297	7,388,130	6,542,444
5. Equipment Leases	1,000,078	639,540	809,624
6. Other Expense	1,015,515	1,055,631	3,000,089
<b>Total Other Expenses</b>	<b>20,033,756</b>	<b>19,565,290</b>	<b>19,029,917</b>
<b>Total Operating Expenses</b>	<b>87,180,713</b>	<b>85,410,148</b>	<b>81,512,244</b>
E. Other Revenue (Expenses) – Net (Specify): <u>Contributions, Grants, Interest Income, etc.</u>	(253,313)	2,560	(11,130)
<b>NET OPERATING INCOME (LOSS)</b>	<b>(2,977,428)</b>	<b>(1,620,079)</b>	<b>3,568,172</b>
F. Capital Expenditures			
Retirement of Principal	-	6,205	6,205
Interest	-	6,205	6,205
<b>Total Capital Expenditures</b>	<b>-</b>	<b>6,205</b>	<b>6,205</b>
<b>NET OPERATING INCOME (LOSS)</b>	<b>(2,977,428)</b>	<b>(1,626,284)</b>	<b>3,561,967</b>
<b>LESS CAPITAL EXPENDITURES</b>			

**October 29, 2014****10:28 am****PROJECTED DATA CHART**

Give information for the two (2) years following the completion of this proposal. The fiscal year begins in January.

	<u>Year 1</u>	<u>Year 2</u>
A. Utilization Data (Lithotripsy Procedures)	52	78
B. Revenue from Services to Patients		
1 Inpatient Services	36,631	54,947
2 Outpatient Services	742,761	1,114,142
3 Emergency Services		
4 Other Operating Revenue (Specify)		
<b>Gross Operating Revenue</b>	<b>779,393</b>	<b>1,169,089</b>
C. Deductions from Gross Operating Revenue		
1 Contractual Adjustments	518,296	777,444
2 Provision for Charity Care	34,293	51,440
3 Provisions for Bad Debt	27,731	41,596
<b>Total Deductions</b>	<b>580,320</b>	<b>870,480</b>
<b>NET OPERATING REVENUE</b>	<b>199,072</b>	<b>298,609</b>
D. Operating Expenses		
1 Salaries and Wages	8,164	12,246
2 Physician Salaries and Wages	-	-
3 Supplies	6,500	9,750
4 Taxes		
5 Depreciation		
6 Rent	-	-
7 Interest, other than capital		
8 Management Fees:		
a. Fees to Affiliates	-	-
b. Fees to Non-Affiliates	-	-
9 Other Expenses		
1 Radiogy, Lab and Anesthesia	6,604	9,906
2 PACU & OR	57,200	85,800
3 Equipment Lease	70,200	105,300
<b>Total Other Expenses</b>	<b>134,004</b>	<b>201,006</b>
<b>Total Operating Expenses</b>	<b>148,668</b>	<b>223,002</b>
E. Other Revenue (Expenses) – Net (Specify)		
<b>NET OPERATING INCOME (LOSS)</b>	<b>50,404</b>	<b>75,607</b>
F. Capital Expenditures		
1 Retirement of Principal		
2 Interest		
<b>Total Capital Expenses</b>	<b>-</b>	<b>-</b>
<b>NET OPERATING INCOME (LOSS)</b>		
<b>LESS CAPITAL EXPENDITURES</b>	<b>50,404</b>	<b>75,607</b>

\*Replacement page #42



6. A. Please provide the current and proposed charge schedules for the proposal. Discuss any adjustment to current charges that will result from the implementation of the proposal. Additionally, describe the anticipated revenue from the proposed project and the impact on existing patient charges.

The average projected gross charge, average projected deduction from operating revenue, and average projected net charge for the two years following the completion of this proposal are presented below:

**Average Projected "Gross Charge" = \$14,988**

**Average Estimated "Deduction" = \$11,160**

**Average Projected "Net Charge" = \$3,828**

These estimates for the proposed project are consistent with the actual experience of Covenant Health (the parent company of MHH) for its existing mobile lithotripsy services at other hospitals prior to the filing of this CON application.

- B. Compare the proposed charges to those of similar facilities in the service area/adjoining service areas, or to proposed charges of projects recently approved by the Health Services and Development Agency. If applicable, compare the proposed charges of the project to the current Medicare allowable fee schedule by common procedure terminology (CPT) code(s).

The "average gross charge" per lithotripsy procedure when the new mobile service begins is estimated to be \$14,988 – with average deduction from operating revenue estimated at \$11,160 and average "net charge" (or net revenue) estimated at \$3,828. These estimates for the proposed project are consistent with the current charges of Covenant Health for its existing mobile lithotripsy services prior to the filing of this CON application.

Currently, the Medicare allowable fees for lithotripsy procedures at community hospitals like MHH are \$ 2,483.55 - \$ 8,333.55:

- Inpatient - \$2,483.55
- Outpatient - without complications \$5,875.84
- Outpatient - with complications \$8,222.55

Additionally, the proposed charges for the project are reasonable considering data available about lithotripsy procedures at other approved sites in Tennessee.

<u>HSDA Approved Lithotripsy Service</u>	<u>Estimated Average Gross Charge</u>
Lakeway Hospital (2013)	\$ 32,456
University Medical Center (2013)	\$ 31,585
Indian Path Medical Center (2013)	\$ 18,186
Physicians Regional Medical Center (2013)	\$ 17,842

Source: Tennessee HSDA Equipment Registry (August 2014)

7. Discuss how projected utilization rates will be sufficient to maintain cost-effectiveness.

The proposed project is both cost-effective and viable. Anticipated utilization rates are sufficient to produce positive cash flow for the project in Year 1, Year 2, and Year 3 – and will be sufficient to maintain operations over time. Additionally, MHH anticipates that a positive Net Operating Income will be achieved for each year of the project, beginning in Year 1.

<u>Projected Annual Utilization</u>	<u>Year 1</u>	<u>Year 2</u>	<u>Year 3</u>
Mobile Lithotripsy Procedures	52	78	104
<u>Financial Feasibility</u>			
Net Operating Revenue	199,072	298,609	398,145
Net Operating Income	50,404	75,607	100,809

Beyond initial conservative projections, it is expected that mobile lithotripsy utilization in the region may actually grow modestly in the foreseeable future due to demographic factors and increasing demand across the region over time.

MHH will continue to serve all patients regardless of race, ethnicity, age, gender, or income level.

8. Discuss how financial viability will be ensured within two years; and demonstrate the availability of sufficient cash flow until financial viability is achieved.

The proposed project is economically feasible and viable. The positive cash flow projected for each year of the project will be sufficient to maintain operations over time – and MHH anticipates that a positive Net Operating Income will be achieved within each year of the project, beginning in Year 1. There is no direct capital expense to MHH or Covenant Health for the proposed project (or related depreciation expense). Regardless, the applicant has adequate financial resources to cover the entire cost of the project as a Covenant Health affiliate.

<u>Projected Annual Utilization</u>	<u>Year 1</u>	<u>Year 2</u>	<u>Year 3</u>
Mobile Lithotripsy Procedures	52	78	104
<u>Financial Feasibility</u>			
Net Operating Revenue	199,072	298,609	398,145
Net Operating Income	50,404	75,607	100,809

9. Discuss the project's participation in state and federal revenue programs, including a description of the extent to which Medicare, TennCare/Medicaid, and medically indigent patients will be served by the project. In addition, report the estimated dollar amount of revenue and percentage of total project revenue anticipated from each of TennCare, Medicare, or other state and federal sources for the proposal's first year of operation.

Historically, MHH has provided a significant level of care to patients participating in TennCare and Medicare funded programs. The proposed mobile lithotripsy project assumes that participation in these government sponsored programs will continue.

The following table projects the estimated dollar amount of gross revenue associated with patients covered by these two government programs.

First Year of Operation		
	Estimated Gross Revenue	% of Gross Revenue
TennCare	\$ 116,909	15%
Medicare	\$ 444,245	57%

10. Provide copies of the balance sheet and income statement from the most recent reporting period of the institution and the most recent audited financial statements with accompanying notes, if applicable. For new projects, provide financial information for the corporation, partnership, or principal parties involved with the project. Copies must be inserted at the end of the application, in the correct alpha-numeric order and labeled as Attachment C, Economic Feasibility-10.

See Attachment C, Economic Feasibility, 10 – Financial Statements

11. Describe all alternatives to this project which were considered and discuss the advantages and disadvantages of each alternative including but not limited to:

- (a) A discussion regarding the availability of less costly, more effective, and/or more efficient alternative methods of providing the benefits intended by the proposal. If development of such alternatives is not practicable, the applicant should justify why not; including reasons as to why they were rejected.

**This CON application seeks approval to initiate lithotripsy services and operate a vendor-owned mobile lithotripsy device that currently exists in the service area. The proposed equipment for the project is a clinically appropriate and proven lithotripsy unit that has plenty of open capacity available to meet the needs of MHH, its medical staff, and its patients for the foreseeable future. Moreover, the proposed arrangement to make mobile lithotripsy equipment available at MHH allows provider flexibility and represents a unique opportunity for orderly and efficient collaboration within Hamblen County.**

**This selected alternative to increasing access to lithotripsy services in Hamblen County is the most practical, cost-effective, efficient, and orderly way to introduce a new lithotripsy service on site at MMH. The project seeks to utilize (i.e. share) medical equipment that already exists within the service area in a manner supported by the existing vendor, that will not be opposed by the only existing provider of mobile lithotripsy services within Hamblen County, and that requires no capital outlay by MHH, it's parent company, or it's medical staff.**

**Other options considered include the following:**

- **Do nothing – not an acceptable option for the MHH medical staff and other community physicians due to increasing demand for lithotripsy services on site at MHH, as well as because of significant outmigration burdens for many patients who need lithotripsy procedures**
- **MHH Acquisition of Lithotripsy Equipment – this option was rejected since it would be more costly to the applicant; would create unneeded, duplicative, and competing excess capacity in the region; would not utilize existing resources available in the service area with open capacity to address needs via an orderly equipment sharing arrangement supported by a reputable and proven vendor.**

- (b) The applicant should document that consideration has been given to alternatives to new construction, e.g., modernization or sharing arrangements. It should be documented that superior alternatives have been implemented to the maximum extent practicable.

**Not applicable. This project requires no construction or renovation expense.**

## **CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE**

1. List all existing health care providers (e.g., hospitals, nursing homes, home care organizations, etc.), managed care organizations, alliances, and/or networks with which the applicant currently has or plans to have contractual and/or working relationships, e.g., transfer agreements, contractual agreements for health services.

**Morristown-Hamblen Hospital has contracts with the following managed care organizations and intends to contract with them for the proposed project as well.**

**Aetna  
Beech Street  
Blue Cross Blue Shield of TN – Commercial (Network P, Network S)  
BlueCare/TennCare  
Blue Cross Blue Shield of TN – Medicare Advantage  
BlueGrass Family Health – Commercial  
CCN – Commercial  
CHA Provider Network – Commercial  
CIGNA (Includes Great West) – Commercial  
Humana ChoiceCare – Commercial  
Humana Medicare Advantage  
Initial Group – Commercial  
MedSave USA – Commercial  
Multiplan – Commercial  
National Provider Network – Commercial  
PHCS – Commercial  
Tri-Care (Champus) – Military  
United HealthCare – Commercial  
United HealthCare Medicare Advantage  
United HealthCare Community Plan /TennCare  
USA Managed Care Organization – Commercial**

**In addition to managed care contracts, the applicant will have appropriate transfer agreements and working arrangements with hospitals and other healthcare organizations.**

2. Describe the positive and/or negative effects of the proposal on the health care system. Please be sure to discuss any instances of duplication or competition arising from your proposal including a description of the effect the proposal will have on the utilization rates of existing providers in the service area of the project.

**The project will have a positive effect on the service area. MHH simply seeks to initiate mobile lithotripsy services at a convenient and well-know location at its main hospital campus. The project proposes to use existing vendor-owned mobile lithotripsy equipment that is currently operational in the service area and that has significant open capacity that is sufficient to meet the needs of MHH patients and physicians in the service area.**

The proposed mobile lithotripsy project will have a positive impact because it expands access to a needed service in the community while enhancing the clinical capabilities of the not-for-profit community hospital Hamblen County. The proposed location of the mobile lithotripsy unit will make scheduling easy and efficient, utilizing existing staff and support infrastructure to ensure a “patient-friendly” and “physician-friendly” environment for needed lithotripsy procedures within the service area. The proposed lithotripsy services will be operated as a fully-integrated component of the MHH campus – providing direct connectivity to the Surgery, Emergency, Imaging, and Medical Staff functions of the hospital. The project will utilize the same qualified leadership and appropriately trained staff that currently support other areas of the medical center.

The project will not have a negative effect on the service area – and does not require unnecessary duplication of healthcare services in the region. This project does not add another mobile lithotripsy unit to the project service area – rather, the project will improve mobile lithotripsy access within the region by initiating such services at another location via the orderly and efficient use of an existing vendor-owned lithotripsy unit that has been underutilized historically. Lakeway Hospital (owned and operated by CHS), the only existing provider of lithotripsy services in the project service area, has provided a letter to confirm that it is not opposed to the project.

The project represents a logical addition to MHH’s existing mix of clinical services within Hamblen County to better serve its patients and affiliated physicians in an orderly manner. Like all other hospital-based services provided by MHH, this project will be accessible to all patients in the region since MHH is a contracted provider with all area TennCare MCOs and has a long history of serving all patients regardless of race, ethnicity, gender, age, or income level. The project addresses evolving community needs and the expressed opinions of providers who serve many patients from the project service area. Moreover, this project reflects the ongoing commitment of MHH to invest in needed community healthcare resources locally – and does not create financial and legal risk for other community healthcare providers.

3. Provide the current and/or anticipated staffing pattern for all employees providing patient care for the project. This can be reported using FTEs for these positions. Additionally, please compare the clinical staff salaries in the proposal to prevailing wage patterns in the service area as published by the Tennessee Department of Labor & Workforce Development and/or other documented sources.

### Staffing Pattern & Wage Comparisons

Position	FTE's	Planned Wage at Estimated Market Rate	MHH Minimum	MHH Maximum
Surgery RN* (Lithotripsy Trained)	< .05 FTE	\$ 23.45 / hour	\$18.10	\$29.60
Pre/Post-Op RN* (Lithotripsy Trained)	< .05 FTE	\$ 23.45 / hour	\$18.10	\$29.60
Surgery Tech* (Lithotripsy Trained)	< .05 FTE	\$ 18.23 / hour	\$13.38	\$21.11
Office and Logistics Support Staff*	< .05 FTE	\$ 11.35 / hour	\$9.26	\$13.70

\* Represents existing staff (FTEs) within the MHH Surgery Department

Source notes: on behalf of its affiliates, including MHH, and for clinically-oriented positions, Covenant Health currently subscribes to and/or participates in the following salary survey sources and might use them individually or in combination to ascertain and establish market competitive salary levels: Tennessee Hospital Association Annual Salary Survey, W.M. Mercer - Integrated Health Network Annual Salary Survey; Towers Watson - Hospital & Healthcare Management Compensation Report; Towers Watson - Hospital & Healthcare Professional, Nursing, & Allied Services Compensation Report; Hospital & Healthcare Comp Services – Homecare Salary and Benefits Survey; Sullivan, Cotter & Associates – Hospital & Healthcare Manager & Executive Comp Survey; Economic Research Institute - Complete Consultant Series (Salary Assessor, Executive Comp Assessor, Geographic Assessor).

4. Discuss the availability of and accessibility to human resources required by the proposal, including adequate professional staff, as per the Department of Health, the Department of Mental Health and Developmental Disabilities, and/or the Division of Mental Retardation Services licensing requirements.

The proposed project will utilize existing Surgery Department leadership and staff from MHH. Additionally, there are no current indications that the required employees for this project will be difficult to identify and/or hire within the proposed service area. MHH and Covenant Health have a proven track record of finding, hiring, and developing excellent clinical staff across service lines in conjunction with affiliated physicians.

5. Verify that the applicant has reviewed and understands all licensing certification as required by the State of Tennessee for medical/clinical staff. These include, without limitation, regulations concerning physician supervision, credentialing, admission privileges, quality assurance policies and programs, utilization review policies and programs, record keeping, and staff education.

The applicant has reviewed and understands all licensing certification as required by the State of Tennessee for medical/clinical staff.

6. Discuss your health care institution's participation in the training of students in the areas of medicine, nursing, social work, etc. (e.g., internships, residencies, etc.).

**Covenant Health affiliated entities, including Morristown-Hamblen Hospital, have a strong history of training many students in clinical areas that enhance community healthcare within East Tennessee. It is likely that the proposed project will benefit from and participate with such ongoing training efforts and relationships with training programs in the region.**

7. (a) Please verify, as applicable, that the applicant has reviewed and understands the licensure requirements of the Department of Health, the Department of Mental Health and Developmental Disabilities, the Division of Mental Retardation Services, and/or any applicable Medicare requirements.

**The applicant has reviewed and understands the licensure requirements of the Department of Health, the Department of Mental Health and Developmental Disabilities, the Division of Mental Retardation Services, and/or any applicable Medicare requirements.**

- (b) Provide the name of the entity from which the applicant has received or will receive licensure, certification, and/or accreditation.

**Licensure: Tennessee Department of Health**

**Accreditation: The Joint Commission**

- (c) If an existing institution, please describe the current standing with any licensing, certifying, or accrediting agency. Provide a copy of the current license of the facility.

**MHH is in good standing with the Tennessee Department of Health (TDH) and The Joint Commission (TJC).**

**See Attachment C, Orderly Development, 7.c. – TDH License and TJC Certificate**

- (d) For existing licensed providers, document that all deficiencies (if any) cited in the last licensure certification and inspection have been addressed through an approved plan of correction. Please include a copy of the most recent licensure/certification inspection with an approved plan of correction.

**MHH has addressed all deficiencies cited in recent certifications and inspections.**

**See Attachment C, Orderly Development, 7.d. – Inspections & Corrections**

8. Document and explain any final orders or judgments entered in any state or country by a licensing agency or court against professional licenses held by the applicant or any entities or persons with more than a 5% ownership interest in the applicant. Such information is to be provided for licenses regardless of whether such license is currently held.

**Not applicable.**



9. Identify and explain any final civil or criminal judgments for fraud or theft against any person or entity with more than a 5% ownership interest in the project.

**Not applicable.**

10. If the proposal is approved, please discuss whether the applicant will provide the Tennessee Health Services and Development Agency and/or the reviewing agency information concerning the number of patients treated, the number and type of procedures performed, and other data as required.

**If requested by the Tennessee Health Services and Development Agency and/or the reviewing Agency, the applicant will provide statistics regarding the number of patients treated, the number and type of procedures performed, and other data as required.**

### PROOF OF PUBLICATION

Attach the full page of the newspaper in which the notice of intent appeared with the mast and dateline intact or submit a publication affidavit from the newspaper as proof of the publication of the letter of intent.

See Attachment – Proof of Publication

### DEVELOPMENT SCHEDULE

Tennessee Code Annotated § 68-11-1609(c) provides that a Certificate of Need is valid for a period not to exceed three (3) years (for hospital projects) or two (2) years (for all other projects) from the date of its issuance and after such time shall expire; provided, that the Agency may, in granting the Certificate of Need, allow longer periods of validity for Certificates of Need for good cause shown. Subsequent to granting the Certificate of Need, the Agency may extend a Certificate of Need for a period upon application and good cause shown, accompanied by a non-refundable reasonable filing fee, as prescribed by rule. A Certificate of Need which has been extended shall expire at the end of the extended time period. The decision whether to grant such an extension is within the sole discretion of the Agency, and is not subject to review, reconsideration, or appeal.

1. Please complete the Project Completion Forecast Chart on the next page. If the project will be completed in multiple phases, please identify the anticipated completion date for each phase.
2. If the response to the preceding question *indicates that the applicant does not anticipate completing the project within the period of validity as defined in the preceding paragraph*, please state below any request for an extended schedule and document the “good cause” for such an extension.

## PROJECT COMPLETION FORECAST CHART

Enter the Agency projected Initial Decision date, as published in Rule 68-11-1609(c): January 2015

Assuming the CON approval becomes the final agency action on that date; indicate the number of days from the above agency decision date to each phase of the completion forecast.

Phase	Days Required	Anticipated Date (Month/Day)
1. Architectural and engineering contract signed	0	N/A
2. Construction documents approved by the Tennessee Department of Health	0	N/A
3. Construction contract signed	0	N/A
4. Building permit secured	0	N/A
5. Site preparation completed	0	N/A
6. Building construction commenced	0	N/A
7. Construction 40% complete	0	N/A
8. Construction 80% complete	0	N/A
9. Construction 100% complete (approved for occupancy)	0	N/A
10. *Issuance of license	0	N/A
11. *Initiation of service	1	February 1-15, 2015
12. Final Architectural Certification of Payment	0	N/A
13. Final Project Report Form (HF0055)	1	April 1, 2015

\* For projects that do NOT involve construction or renovation: please complete items 10 and 11 only.

Note: If litigation occurs, the completion forecast will be adjusted at the time of the final determination to reflect the actual issue date.

COUNTY OF KNOX

Mr. P. L. VP STRATEGIC PLANNING  
+ DEVELOPMENT

Jamie Hopkins

My Commission expires

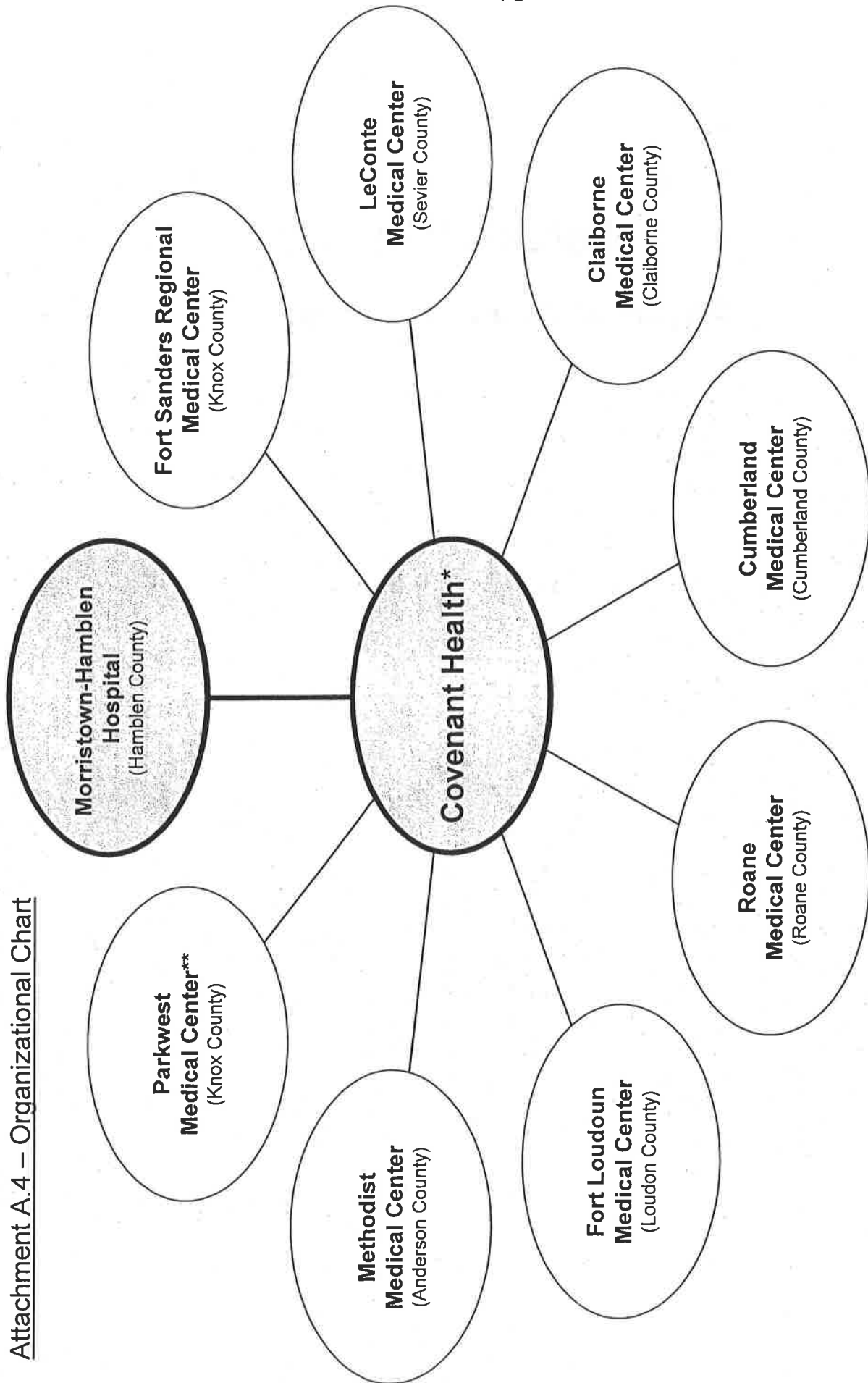
9/30/2015



## **ATTACHMENTS**

**Attachment A.4**  
**Organizational Chart**

# Attachment A.4 – Organizational Chart



\* For clarity, only Covenant Health's acute care hospitals have been listed.

\*\* Peninsula Hospital (Psychiatric/Behavioral Health) is a division/satellite of Parkwest Medical Center.

**Attachment B.I.a**

**Physician Support Letters**





# MORRISTOWN-HAMBLEN HEALTHCARE SYSTEM

Covenant  
HEALTH

OCT 13 '14 AM 10:21

908 West Fourth  
North St.

P.O. Box 1178

Morristown, TN 37816

(423) 492-9000

www.mhlhs.org

September 16, 2014

Ms. Melanie M. Hill  
Executive Director  
Tennessee Health Services and Development Agency  
Andrew Jackson Building, Ninth Floor  
502 Deaderick Street  
Nashville, TN 37243

Dear Ms. Hill:

As the Chief of Staff for Morristown-Hamblen Hospital, I am writing in support of the Certificate of Need filed for lithotripsy services at our hospital. There are a significant number of stone cases in our area, and we now have a well-qualified urologist at our hospital to treat these patients locally. Having this service at Morristown-Hamblen Hospital will enable us to better care for our patients through more timely and efficient care of patients requiring lithotripsy procedures – and to reduce the significant pain and discomfort commonly associated with kidney stones.

Approval of this project for mobile lithotripsy services will improve patient access in our region, reduce patient burdens, and address specific clinical needs of our growing medical staff.

Sincerely,

Shahin Assadnia, M.D.  
Chief of Staff  
Morristown Hamblen Healthcare System

Emergency & Critical Care

Heart, Lung & Vascular Center

Joint & Spine Center

Laboratory Services Center

Morristown Regional  
Cancer Center

Morristown Regional  
Diagnostic Center

Prompt Family Care

Senior Services

Sleep Disorder Center

Surgical Services Center

Wellness of Women

Women's & Children's Center

Women's Health Specialist

**TEAMHealth.**

265 Brookview Centre Way Suite 400 • Knoxville TN 37919  
p 800.818.1498 • 865.693.1000  
[www.teamhealth.com](http://www.teamhealth.com)

September 12, 2014

Melanie M. Hill, Executive Director  
State of Tennessee  
Health Services and Development Agency  
Andrew Jackson Building, Ninth Floor  
502 Deaderick Street  
Nashville, TN 37243

RE: Morristown-Hamblen Hospital, Mobile Lithotripsy Certificate of Need

Dear Ms. Hill:

As the Medical Director of the Emergency Department at Morristown Hamblen Hospital, I am writing in support of the CON application for the much needed mobile lithotripsy services at Morristown Hamblen Hospital.

We see over 300 kidney stone related patients each year. While not all of these patients are candidates for lithotripsy procedures, having this important clinical service available at our facility would reduce the burdens of travel time, referral logistics, and significant discomfort for the many patients who would benefit from having the service available on site.

On behalf of the many physicians and staff with whom I work, I ask the Agency to support this Certificate of Need application for mobile lithotripsy services which will benefit the patient population we serve from Hamblen and surrounding counties.

Sincerely,



Jackie Livesay, MD

Medical Director

MHHS Emergency Department

**Philip Serbin, MD**

Phone: 423-581-6084 • Fax: 423-581-6078

September 15, 2014

Melanie M. Hill, Executive Director  
State of Tennessee  
Health Services and Development Agency  
Andrew Jackson Building, Ninth Floor  
502 Deaderick Street  
Nashville, TN 37243

Dear Ms. Hill:

As a urologist practicing at Morristown-Hamblen Hospital, I have seen a significant and growing number of patients with kidney stones that would benefit greatly from lithotripsy services at our hospital campus. This service is currently not available at our hospital.

Lithotripsy is a safe and effective method of treating kidney stones, and I believe the utilization projections within the MHH certificate of need application are both realistic and conservative based upon the patient population in our region and my clinical experience here in Morristown, Tennessee. Moreover, as a physician who has been caring for urology patients for more than 20 years, I believe lithotripsy is a needed service at our hospital and would benefit our patients and community greatly.

I respectfully urge members of the Tennessee Health Services and Development Agency to approve the CON application for mobile lithotripsy services at Morristown Hamblen Hospital.

Sincerely,



Philip Serbin, MD

Urologist

**Attachment B.I.b**

**Letter from CHS/Lakeway Hospital**



July 22, 2014

*Ms. Melanie M. Hill, Executive Director  
State of Tennessee  
Health Services and Development Agency  
Andrew Jackson Building, Ninth Floor  
502 Deaderick St  
Nashville, TN 37243*

Re: Morristown-Hamblen Healthcare System- Lithotripsy

Dear Ms. Hill,

We have received communication from Leadership at Morristown-Hamblen Healthcare System that they are exploring opportunities to perform Lithotripsy. If or when this happens we would not oppose their application.

If you have any further questions, please contact me at 423-522-6004.

Sincerely,

A handwritten signature in dark ink, appearing to read "Clyde Wood", is written over the printed name.

Clyde Wood  
Chief Executive Officer

**Attachment B.II.E.2**

**FDA Approval**



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 25 2004

Mr. Anil Dhingra  
VP and COO  
Medispec Ltd.  
12850 Middlebrook Rd., Suite 1  
GERMANTOWN MD 20874

Re: K040461

Trade/Device Name: Econolith™ E3000, Model 3000 (SW-6)  
Regulation Number: 21 CFR §876.5990  
Regulation Name: Extracorporeal shockwave lithotripter  
Regulatory Class: II  
Product Code: 78 LNS  
Dated: May 4, 2004  
Received: May 4, 2004

Dear Mr. Dhingra:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2

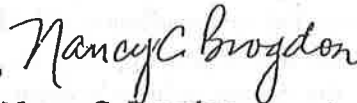
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure



**Indications for Use**510(k) Number (if known): K040461Device Name: Econolith™ E3000**Indications For Use:** The Econolith™ E3000 is indicated for use in non-invasive fragmentation of upper urinary tract stones between 5 and 20 mm in size.Prescription Use ☒  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUING ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

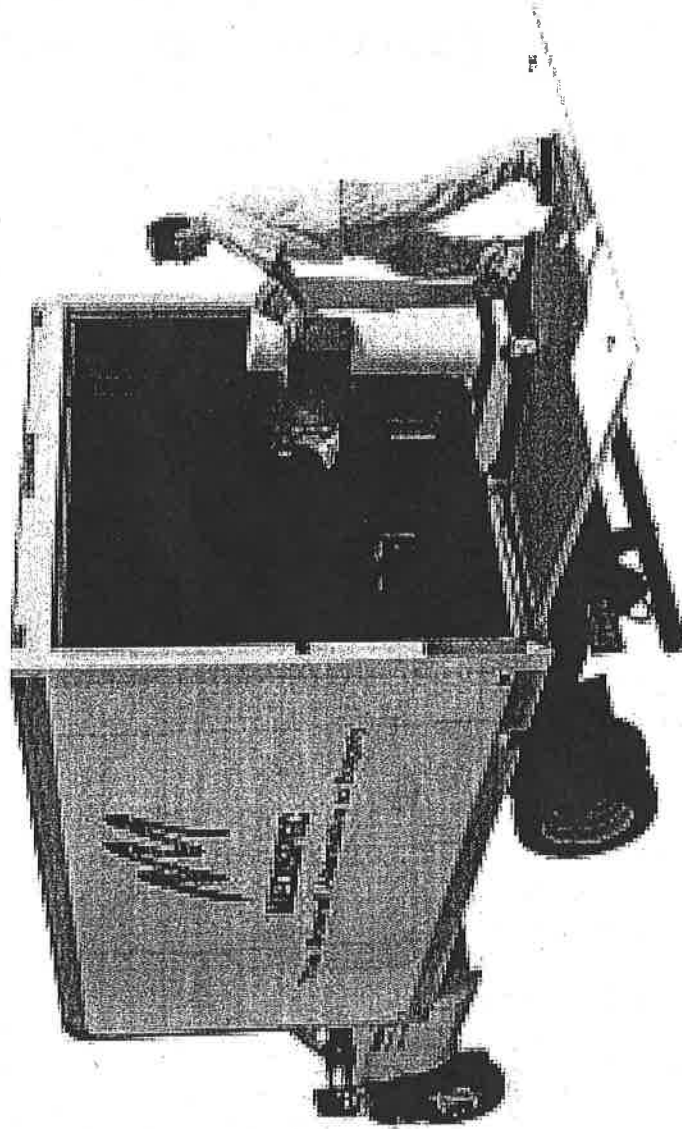
Nancy Brogdon  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices510(k) Number K040461

**Attachment B.II.E.2**

**Picture of Mobile Lithotripsy Equipment**

## **Attachment B.II.E.2: Picture of Mobile Lithotripsy Equipment**

*Medispec Econolith E3000 (Extracorporeal Shockwave Lithotripsy System)*



**Attachment B.II.E.2.d**

**Equipment FMV Letter**



---

The **Sound** Alternative to Surgery

September 5, 2014

Morristown-Hamblen Hospital  
903 West Fourth North Street  
Morristown, TN 37814

Dear Ms. Amy Herndon:

Medispec Ltd. proposes to use our Econolith™ E3000, Model 3000 (SW-6) Lithotripsy Device, which is currently providing service to Lakeway Regional Hospital, located at 726 McFarland St, Morristown, TN 37814, to provide services at Morristown-Hamblen Hospital. The Equipment is being underutilized. This will allow Morristown-Hamblen Hospital to share the existing lithotripsy equipment in the service area in collaboration with Medispec and Lakeway Regional Hospital to address community needs.

The Fair Market Value (FMV) of existing equipment is \$245,000.00.

Sincerely,

Anil Dhingra  
Vice President & Chief Operating Officer  
Medispec Ltd.

**See Attachment B.II.E.3**  
**Equipment Lease Proposal**



# QUOTATION

MEDISPEC LTD.  
203 Perry Parkway, Suite 6  
Gaithersburg, MD 20877  
888-663-3477

QUOTATION

No. 14085

Sales Representative: Kurt Schulte  
Date: July 31, 2014  
Delivery Date: 30-45 days ARO  
Valid Until: January 31, 2015

TO : Morristown-Hamblen Healthcare System  
Attn: Ms. Amy Herndon, CFO  
908 West Fourth North Street  
Morristown, TN 37814

WE SUBMIT THE FOLLOWING 1 PAGE QUOTATION

QTY.	SYSTEM	DESCRIPTION OF EQUIPMENT AND/OR SERVICES	FEE PER USE
1	Econolith™ E3000, Model 3000 (SW-6)	<p><b>MEDISPEC EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY SYSTEM*</b></p> <p>One (1) Shock Wave Generator &amp; Control Unit One (1) Standard 4-axis Treatment Table One (1) Operation &amp; Service Manual</p> <p><b>Price per procedure:</b></p> <p><b><i>INCLUDES ALL CONSUMABLE PARTS FOR TERM OF CONTRACT</i></b></p> <p>Price includes on-site installation, and training.</p>	\$1,350.00 each

This agreement is entered into between Medispec Ltd. and the undersigned customer in consideration of the payments provided for in this agreement. Subject to the terms and conditions set forth on the supplement of this agreement, Medispec Ltd. agrees to supply the equipment listed above.

## Special Terms:

1. The above fee per use proposal is based on a commitment of three (3) years.
2. Customer agrees to pay for a minimum of nine (9) procedures per quarter. The full year(s) billing for this agreement will run thirty-six (36) months from the first of the month following the date of installation.
3. \*Customer to provide a suitable C-arm to use in conjunction with the Lithotripter.
4. Customer has the option to have Medispec provide transportation of the ESWL system (without C-arm) between Lakeway Regional Hospital and Morristown-Hamblen Hospital, on a predetermined schedule, for a charge of \$300 per transport.
5. The price includes on site installation, end-user training, equipment maintenance and supplies for the term of the agreement.
6. Customer to provide personnel to operate the equipment.
7. Customer will be responsible for the payment of any Federal, State or County taxes related to the Equipment.
8. Payment term: Net thirty (30) days.

CUSTOMER

SIGNATURE of  
Authorized Person:

PRINT NAME & TITLE:

DATE:

**MEDISPEC LTD. ("MEDISPEC"), OFFICIAL TERMS AND CONDITIONS OF ESWL RENTAL**

1. **Delivery, Installation, billing start date and Training.**
  - a. Medispec, Ltd. will, at its cost and expense, deliver and install the Equipment in a location specified by Customer that is suitable for the use and operation of the Equipment (the "Equipment Location"). Customer shall be responsible for ensuring that the Equipment Location is suitable for the use and operation of the Equipment. Customer shall not remove the Equipment from Equipment Location unless it shall receive Medispec's written permission.
  - b. The term of this Agreement will begin on the first day the equipment is used for Patient Treatments at Equipment Location. This Agreement includes a minimum number of treatments to be billed per month. Medispec will bill the actual number of treatments from the date of installation to the first of the following month.
  - c. Medispec will provide, at its cost and expense, on-site, applications training to the staff of Customer in the use of the Equipment. The maximum number of such training sessions will be two (2) per year. For any additional training sessions, Medispec shall charge Customer a mutually agreeable price. Each training session will last for a period of two (2) days and shall include a complete on-site, applications training for the use and operation of the Equipment.
2. **Default and Remedies.**  
If Customer i) fails to pay any payment hereunder within sixty days of date due or ii) fails to perform any of the other terms, covenants of conditions of this Agreement after thirty (30) days written notice, or iii) becomes insolvent or makes an assignment for the benefit of creditors, or iv) a receiver, trustee, conservator or liquidator is appointed on behalf of Customer with or without Customer's consent, Customer shall be in default under this Agreement and Medispec may, to the extent permitted by applicable law, exercise any one or more of the following remedies: I) declare due, sue for and receive from Customer the sum of all Usage Fees and other amounts due and owing under this Agreement; II) take immediate possession of the Equipment; III) require Customer to return all Equipment at Customer's expense to a place reasonably designated by Medispec; IV) Medispec shall charge Customer for all reasonable expenses incurred in connection with the enforcement of any remedies, including all costs of collection, reasonable attorney's fees, and court costs.
3. **License and Permits.**  
At all times during the Term of this Agreement, Customer will maintain all licenses, permits and other certifications required by applicable law and regulation for Customer's provision of ESWL Services.
4. **Insurance.**  
During the term of this Agreement, Customer shall maintain or cause to maintain the following insurance coverage from and with an insurance company having a rating of A.M. Best and Company of at least "A-" or higher:
  - a. Customer shall maintain malpractice insurance coverage for its insurance provision of medical and Hospital Services where the limits of such insurance coverage are no less than One Million Dollars (\$1,000,000.00) per occurrence and Three Million Dollars (\$3,000,000.00) aggregate.
  - b. Customer shall maintain a One Million Dollar (\$1,000,000.00) general liability policy covering all personal property liability resulting from or related to Customer and its facilities. Customer agrees to keep the Equipment fully insured against loss, naming Medispec as loss payee. Customer agrees to include Medispec as an insured party on the policy and to provide Medispec with certificates or other evidence of insurance.
  - c. Each physician using or operating the Equipment will, at all times, maintain individual or group practice malpractice insurance having coverage of at least One Million Dollars (\$1,000,000) per occurrence and Three Million Dollars (\$3,000,000.00) aggregate.
5. **Equipment Maintenance.**  
Medispec shall be responsible for all maintenance of the Equipment. Customer shall notify Medispec immediately of any malfunction to the Equipment. Medispec shall, within forty eight (48) hours after being notified by Customer, send a technician to repair the Equipment. Customer shall provide Medispec with access to the Equipment at reasonable times during which the Equipment is located at the Equipment location.
6. **Damage.**  
Customer shall be responsible for any damage caused to the Equipment while the Equipment is located at Equipment Location except for ordinary wear and tear or for damage caused by the actions or inactions of Employees and Representatives of Medispec.
7. **Confidentiality.**  
Customer shall keep confidential and secure any manuals or any other documentation related to the use and operation of the Equipment that are provided by Medispec and shall return all such documents and copies of such documents to Medispec at the end of this Agreement.
8. **Indemnification.**  
Customer shall not be liable for any claim, injury, demand or judgement arising out of any action or failure to act by Medispec, its agents or employees. Medispec shall not be liable for any claim, injury, demand or judgement arising out of any actions or failure to act by Customer, its agents or employees.
9. **Assignment.**  
Medispec may without notice to or consent from Customer sell, assign or transfer this Agreement.
10. **Governing Law.**  
This Agreement shall be governed by and construed in accordance with the laws of the State of Maryland. Any disputes under this Agreement shall be settled by binding arbitration in Maryland before a single arbitrator of the American Arbitration Association.

**CUSTOMER**

SIGNATURE of  
Authorized Person: \_\_\_\_\_

PRINT NAME & TITLE: \_\_\_\_\_

DATE: \_\_\_\_\_

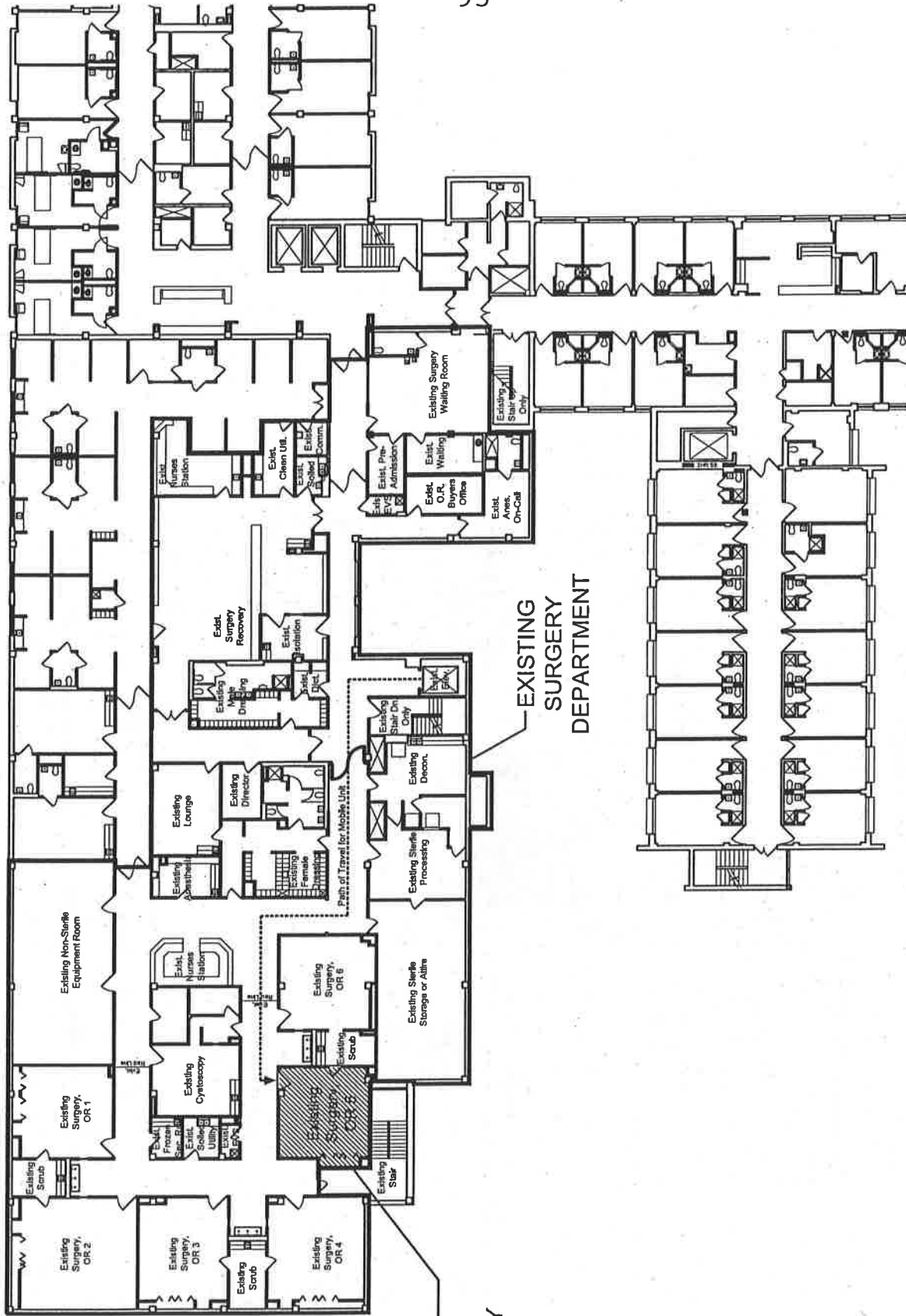


**Attachment B.III.A**

**Plot Plan of the Site**

**Attachment B.IV**

**Floor Plan**



PROPOSED  
MOBILE  
LITHOTRIPSY  
LOCATION -  
EXISTING  
SURGERY  
DEPT., OR 5

EXISTING  
SURGERY  
DEPARTMENT



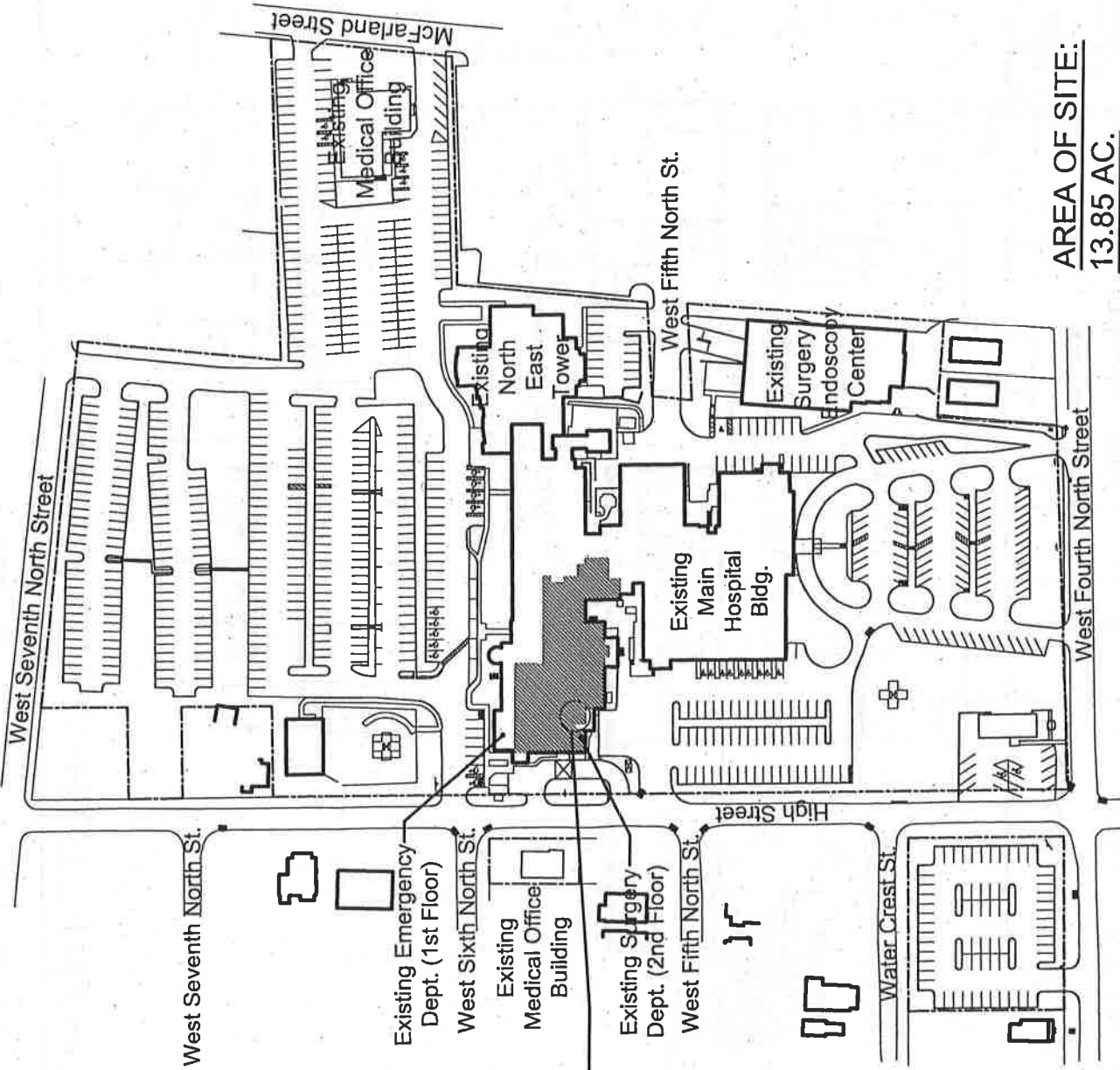
# MHH: MOBILE LITHOTRIPSY C.O.N.

908 West Fourth North St., Morristown, TN 37814

SURGERY DEPARTMENT FLOOR PLAN

09-10-2014





AREA OF SITE:  
13.85 AC.

# MHH: MOBILE LITHOTRIPSY C.O.N.

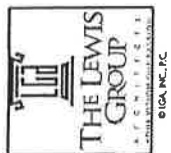
908 West Fourth North St., Morristown, TN 37814

SITE PLAN

09-10-2014



908 West Fourth North St., Morristown, TN 37814



**Attachment C.1.a.1**

**TDH Lithotripsy Need Projections by County**

# Attachment C.1.a.1: TDH Lithotripsy Need Projections by County

## EXTRA-CORPOREAL SHOCK WAVE LITHOTRIPSY NEED PROJECTIONS BY COUNTY AND STATE TOTAL, 2013 DATA, PROJECTED TO 2017

STATE UTILIZATION RATE 0.0013781

COUNTY	PROJ POP	NEED
TENNESSEE	6,772,022	9,333
ANDERSON	77,582	107
BEDFORD	49,693	68
BENTON	16,136	22
BLED SOE	12,579	17
BLOUNT	133,389	184
BRADLEY	106,448	147
CAMPBELL	42,315	58
CANNON	14,437	20
CARROLL	27,890	38
CARTER	57,548	79
CHEATHAM	40,544	56
CHESTER	17,866	25
CLAIBORNE	33,110	46
CLAY	7,667	11
COCKE	38,143	53
COFFEE	56,107	77
CROCKETT	14,644	20
CUMBERLAND	59,573	82
DAVIDSON	676,131	932
DECATUR	12,009	17
DEKALB	19,079	26
DICKSON	51,683	71
DYER	38,345	53
FAYETTE	43,819	60
FENTRESS	18,827	26
FRANKLIN	41,842	58
GIBSON	51,952	72
GILES	29,282	40
GRAINGER	23,513	32
GREENE	71,216	98
GRUNDY	13,300	18

COUNTY	PROJ POP	NEED
HAMBLETON	65,181	90
HAMILTON	352,340	486
HANCOCK	6,622	9
HARDEMAN	26,106	36
HARDIN	26,184	36
HAWKINS	58,056	80
HAYWOOD	17,999	25
HENDERSON	28,507	39
HENRY	32,898	45
HICKMAN	24,608	34
HOUSTON	8,441	12
HUMPHREYS	18,551	26
JACKSON	11,465	16
JEFFERSON	56,054	77
JOHNSON	18,098	25
KNOX	470,092	648
LAKE	9,533	13
LAUDERDALE	27,146	37
LAWRENCE	42,398	58
LEWIS	12,178	17
LINCOLN	35,340	49
LOUDON	52,629	73
MCMINN	53,956	74
MCNAIRY	27,129	37
MACON	23,894	33
MADISON	100,685	139
MARION	28,880	40
MARSHALL	31,783	44
MAURY	82,991	114
MEIGS	12,559	17
MONROE	47,561	66
MONTGOMERY	197,517	272

COUNTY	PROJ POP	NEED
MOORE	6,389	9
MORGAN	21,953	30
OBION	31,247	43
OVERTON	22,833	31
PERRY	8,083	11
PICKETT	4,945	7
POLK	16,568	23
PUTNAM	81,219	112
RHEA	34,480	48
ROANE	54,310	75
ROBERTSON	73,421	101
RUTHERFORD	320,172	441
SCOTT	21,931	30
SEQUATCHIE	15,747	22
SEVIER	98,873	136
SHELBY	951,669	1,312
SMITH	20,104	28
STEWART	13,855	19
SULLIVAN	160,584	221
SUMNER	180,639	249
TIPTON	66,612	92
TROUSDALE	8,478	12
UNICOI	18,487	25
UNION	19,509	27
VAN BUREN	5,459	8
WARREN	40,990	56
WASHINGTON	136,509	188
WAYNE	16,748	23
WEAKLEY	39,277	54
WHITE	27,670	38
WILLIAMSON	218,093	301
WILSON	131,118	181

DATA SOURCES: HEALTH SERVICES AND DEVELOPMENT AGENCY EQUIPMENT REGISTRY.

HEALTH STATISTICS POPULATION ESTIMATES 2013.

UNIVERSITY OF TENNESSEE, CENTER FOR BUSINESS AND ECONOMIC RESEARCH 2010-2020 POPULATION PROJECTIONS.

PREPARED BY:

TENNESSEE DEPARTMENT OF HEALTH, DIVISION OF POLICY, PLANNING AND ASSESSMENT, OFFICE OF HEALTH STATISTICS.

Run: Aug 2014

**Attachment C.1.a.3**

**Service Area Lithotripsy Providers and Utilization**



## Attachment C.1.a.3

### Health Care Providers that Operate Lithotripsy Equipment in CON Project Service Area

Health Care Providers that Utilize Lithotripters - Payor Source

Source: HSDA Medical Equipment Registry - 8/4/2014

County	Provider Type	Provider	Year	Number	Mobile ?	Mobile Days Used	Medicare		TennCare/Medicaid		Managed Care/Commercial		Self Pay/Other		Total	
							Procedures	Gross Charges	Procedures	Gross Charges	Procedures	Gross Charges	Procedures	Gross Charges	Procedures	Gross Charges
Hamblen	HOSP	Lakeway Regional Hospital	2010	1	Mobile (Full)	7 days/week	28	\$738,550.00	43	\$1,136,130.00	45	\$1,186,157.00	2	\$52,560.00	118	\$3,113,497.00
Hamblen	HOSP	Lakeway Regional Hospital	2011	1	Mobile (Full)	7 days/week	3	\$87,119.00	3	\$87,981.00	10	\$293,559.00	2	\$58,367.00	18	\$527,026.00
Hamblen	HOSP	Lakeway Regional Hospital	2012	1	Mobile (Full)	7 days/week	7	\$216,187.00	10	\$299,108.00	19	\$578,967.00	6	\$179,169.00	42	\$1,273,431.00
Hamblen	HOSP	Lakeway Regional Hospital	2013	1	Mobile (Full)	7 days/week	2	\$63,823.00	2	\$67,092.00	1	\$32,728.00	1	\$31,095.00	6	\$194,738.00

**Attachment C.1.a.3**

**Service Area Lithotripsy Patient Destinations**

### Attachment C.1.a.3: Service Area Lithotripsy Patient Destinations

#### Health Care Providers that Served Residents Who Utilized Lithotripters

Source: Medical Equipment Registry - 8/4/2014

Provider County	Provider Type	Provider	Year	Patient County	Number of Procedures
Anderson	HOSP	Methodist Medical Center - Oak Ridge	2013	Claiborne	1
Knox	HOSP	Fort Sanders Regional Medical Center	2013	Claiborne	1
Knox	HOSP	North Knoxville Medical Center	2013	Claiborne	8
Knox	HOSP	Parkwest Medical Center	2013	Claiborne	4
Knox	HOSP	Physicians Regional Medical Center	2013	Claiborne	3
Knox	HOSP	University of Tennessee Medical Center	2013	Claiborne	16
Washington	HOSP	Franklin Woods Community Hospital	2013	Claiborne	1
Knox	HOSP	Fort Sanders Regional Medical Center	2013	Cocke	5
Knox	HOSP	North Knoxville Medical Center	2013	Cocke	7
Knox	HOSP	Parkwest Medical Center	2013	Cocke	21
Knox	HOSP	Physicians Regional Medical Center	2013	Cocke	2
Knox	HOSP	Turkey Creek Medical Center	2013	Cocke	4
Knox	HOSP	University of Tennessee Medical Center	2013	Cocke	11
Sevier	HOSP	LeConte Medical Center	2013	Cocke	1
Knox	HOSP	Fort Sanders Regional Medical Center	2013	Grainger	4
Knox	HOSP	North Knoxville Medical Center	2013	Grainger	7
Knox	HOSP	Parkwest Medical Center	2013	Grainger	7
Knox	HOSP	Physicians Regional Medical Center	2013	Grainger	4
Knox	HOSP	University of Tennessee Medical Center	2013	Grainger	10
Sullivan	HOSP	Holston Valley Medical Center	2013	Grainger	2
Knox	HOSP	Fort Sanders Regional Medical Center	2013	Hamblen	13
Knox	HOSP	North Knoxville Medical Center	2013	Hamblen	7
Knox	HOSP	Parkwest Medical Center	2013	Hamblen	18
Knox	HOSP	Physicians Regional Medical Center	2013	Hamblen	6
Knox	HOSP	University of Tennessee Medical Center	2013	Hamblen	33
Sullivan	HOSP	Holston Valley Medical Center	2013	Hamblen	2
Sullivan	HOSP	Indian Path Medical Center	2013	Hamblen	1
Bradley	HOSP	Skyridge Medical Center	2013	Jefferson	2
Knox	HOSP	Fort Sanders Regional Medical Center	2013	Jefferson	16
Knox	HOSP	North Knoxville Medical Center	2013	Jefferson	19
Knox	HOSP	Parkwest Medical Center	2013	Jefferson	28
Knox	HOSP	Physicians Regional Medical Center	2013	Jefferson	2
Knox	HOSP	Turkey Creek Medical Center	2013	Jefferson	7
Knox	HOSP	University of Tennessee Medical Center	2013	Jefferson	19
Sevier	HOSP	LeConte Medical Center	2013	Jefferson	1

**293**

**Service Area Total (2013)**

**Attachment C.1.a.3-4**

**Letter from Lakeway Hospital RE: MHH Lithotripsy Project**



July 22, 2014

*Ms. Melanie M. Hill, Executive Director  
State of Tennessee  
Health Services and Development Agency  
Andrew Jackson Building, Ninth Floor  
502 Deaderick St  
Nashville, TN 37243*

Re: Morristown-Hamblen Healthcare System- Lithotripsy

Dear Ms. Hill,

We have received communication from Leadership at Morristown-Hamblen Healthcare System that they are exploring opportunities to perform Lithotripsy. If or when this happens we would not oppose their application.

If you have any further questions, please contact me at 423-522-6004.

Sincerely,

A handwritten signature in dark ink, appearing to read "Clyde Wood", is written over a light-colored background.

Clyde Wood  
Chief Executive Officer

**Attachment C.1.a.9**

**MHH Transfer Agreements**

**MHH: Key Patient Transfer Agreements with Area Hospitals & Nursing Homes**

<b>Name of your hospital:</b>	<b>Morristown-Hamblen</b>
<b>Person completing chart:</b>	Lesa Reed
<b>Telephone # for clarification questions:</b>	423-492-5016

<b>Hospital Names?</b>	<b>Patient Types Covered by Agreement?</b>
Baptist Hospital of Cocke Count (Now Tennova)	hospital patients
Bristol Regional Medical Center (Wellmont)	hospital patients
Cherokee Mental Health	emotionally ill patients
Claiborne County Hospital (Now Covenant)	hospital patients
Cocke County Baptist Hospital (Now Tennova)	hospital patients
East Tennessee Children's	children
Park West	hospital patients
Ft. Sanders Regional	hospital patients
Human Services Community Services Clinic	hospital patients
Johnson City Medical Center	hospital patients
Lakeway Regional Hospital	hospital patients
Laughlin Memorial Hospital (Greeneville)	hospital patients
Mental Health Transportation with Sheriff Hamblen County	hospital patients
Peninsula Hospital (Louisville)	emotionally ill patients
Shriners Hospital - Cincinnati	children
St. Marys - Jefferson City (Now Tennova)	hospital patients
St. Marys - Knoxville (Now Tennova)	hospital patients
Takoma Adventist Hospital (Greeneville)	hospital patients
University Health System (UT)	hospital patients
University of Tennessee Pediatric Transfer	children
Vanderbilt University	hospital patients
Wellmont Holston Valley (Kingsport)	hospital patients
Woodridge Psychiatric Hospital (Johnson City)	emotionally ill patients

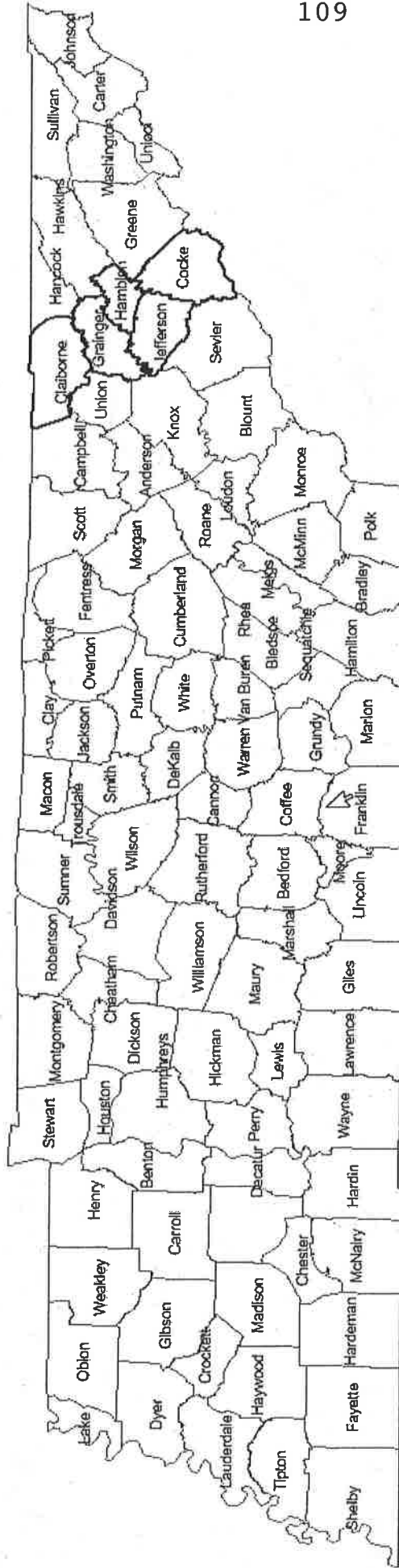
<b>Nursing Home Names?</b>	<b>Patient Types Covered by Agreement?</b>
Baptist Convalescent Center (Now Tennova)	nursing home patients/rehab
Brakebill Nursing Home	nursing home patients/rehab
Hancock Manor	nursing home patients/rehab
Heritage Center (Life Care)	nursing home patients/rehab
Heritage Manor of Rogersville	nursing home patients/rehab
Jefferson City Health and Rehab	nursing home patients/rehab
Jefferson County Nursing Home	nursing home patients/rehab
Laughlin Health Care Center	nursing home patients/rehab
Laurel Manor Health Care	nursing home patients/rehab
Life Care of Jefferson City	nursing home patients/rehab
Life Care of Morristown	nursing home patients/rehab
Mariner Health Care	nursing home patients/rehab
Morning Point Assisted Living	nursing home patients/rehab
Ridgeview Terrace (Rutledge)	nursing home patients/rehab
The Terrace (Morristown)	nursing home patients/rehab

**Attachment C.3**

**Service Area Maps**



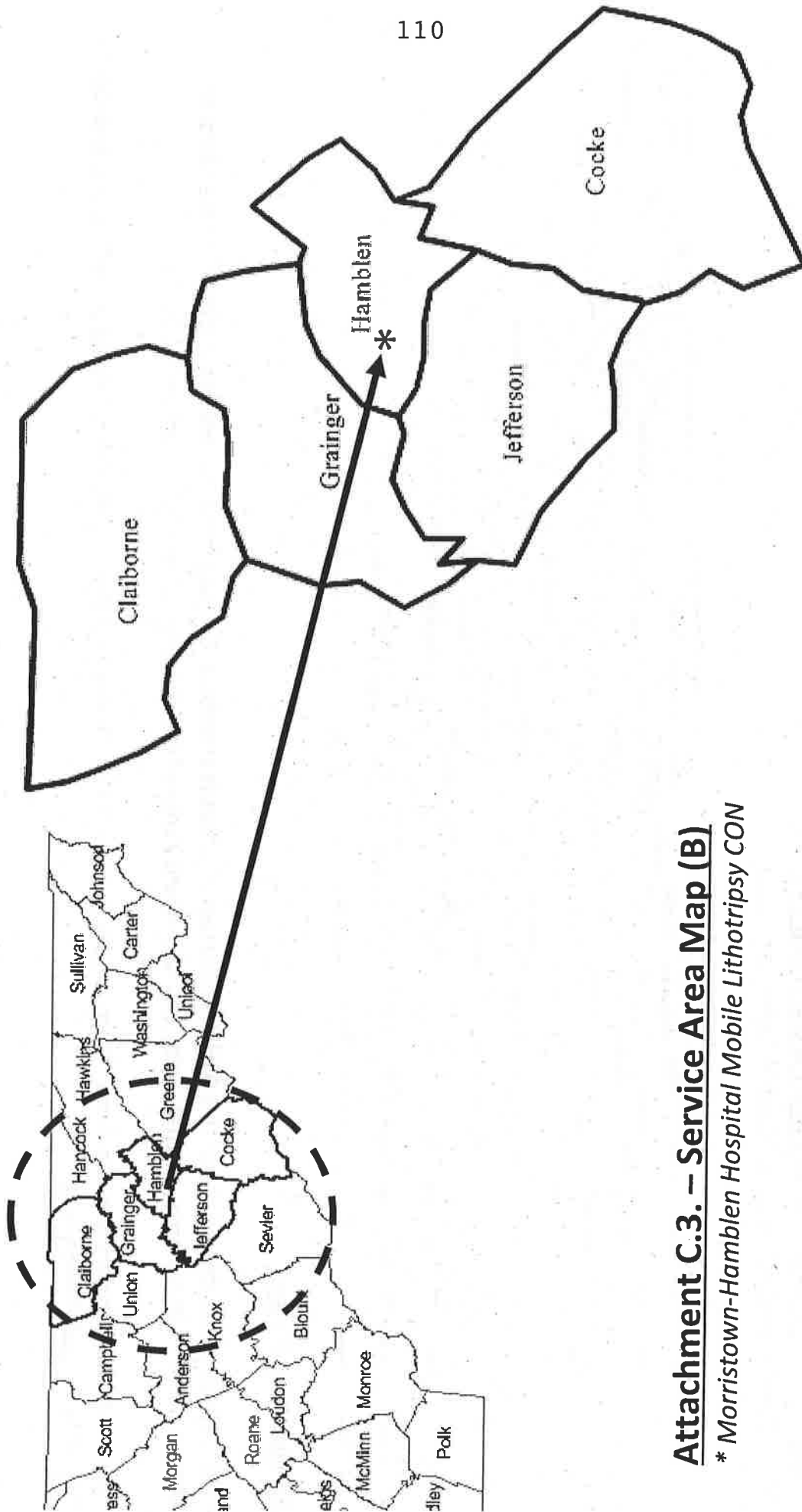
**Attachment C.3. – Service Area Map (A)**  
***Morristown-Hamblen Hospital Mobile Lithotripsy CON***



**Service Area Notes:**

The “primary service area” for this MHH lithotripsy project is Hamblen County from a traditional planning standpoint. Most of MHH’s inpatients, outpatients, and emergency department patients reside in Hamblen County.

However, the “Project Service Area” from a CON perspective includes Hamblen, Claiborne, Grainger, Jefferson, and Cocke Counties in East Tennessee.



### **Attachment C.3. – Service Area Map (B)**

**\* Morristown-Hamblen Hospital Mobile Lithotripsy CON**

**Attachment C.5**

**Health Care Providers that Operate Lithotripsy Equipment in  
CON Project Service Area**

## Attachment C.5

### Health Care Providers that Operate Lithotripsy Equipment in CON Project Service Area

Health Care Providers that Utilize Lithotripters - Payor Source

Source: HSDA Medical Equipment Registry - 8/4/2014

County	Provider Type	Provider	Year	Number	Mobile ?	Mobile Days Used	Medicare		TennCare/Medicaid		Managed Care/Commercial		Self Pay/Other		Total	
							Procedures	Gross Charges	Procedures	Gross Charges	Procedures	Gross Charges	Procedures	Gross Charges	Procedures	Gross Charges
Hamblen	HOSP	Lakeway Regional Hospital	2010	1	Mobile (Full)	7 days/week	28	\$738,550.00	43	\$1,136,130.00	45	\$1,186,157.00	2	\$52,660.00	118	\$3,113,497.00
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Hamblen	HOSP	Lakeway Regional Hospital	2013	1	Mobile (Full)	7 days/week	2	\$63,823.00	2	\$67,092.00	1	\$32,728.00	1	\$31,095.00	6	\$194,738.00

**Attachment C, Economic Feasibility, 2**

**Documentation of Funding Type**

JOHN T. GEPPi  
Executive VP/CFO



October 1, 2014

Ms. Melanie Hill  
Executive Director  
Tennessee Health Services and Development Agency  
500 Deaderick Street, Suite 850  
Nashville, TN 37243

***Re: Adequate Funding for Morristown-Hamblen Hospital – Lithotripsy Services CON***

Dear Ms. Hill:

Covenant Health has sufficient cash reserves to complete the proposed project for Morristown-Hamblen Hospital (MHH) at the estimated total cost \$328,900 for certificate of need purposes. However, there is no required capital outlay by either MHH or Covenant Health for this project which simply creates operational access to a vendor-owned mobile lithotripsy unit via a "per-procedure" equipment lease arrangement.

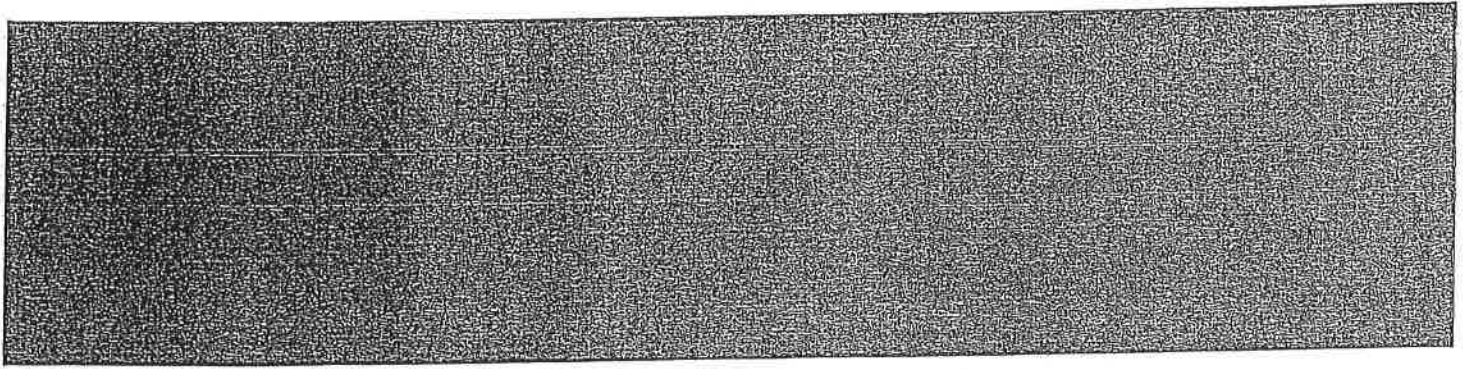
Respectfully,

A handwritten signature in black ink that reads "John Geppi".

John Geppi  
Executive Vice President/Chief Financial Officer  
Covenant Health

**Attachment C, Economic Feasibility, 10**

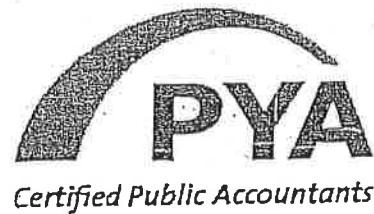
**Financial Statements**



## **COVENANT HEALTH**

### **Audited Consolidated Financial Statements**

**Years Ended December 31, 2013 and 2012**





**COVENANT HEALTH***Audited Consolidated Financial Statements**Years Ended December 31, 2013 and 2012*

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Independent Auditor's Report.....1

*Audited Consolidated Financial Statements*

Consolidated Balance Sheets .....	3
Consolidated Statements of Operations and Changes in Net Assets .....	5
Consolidated Statements of Cash Flows.....	7



PERSHING YOAKLEY & ASSOCIATES, P.C.  
One Cherokee Mills, 2220 Sutherland Avenue  
Knoxville, TN 37919

p: (865) 673-0844 | f: (865) 673-0173  
www.pyapc.com

## INDEPENDENT AUDITOR'S REPORT

To the Board of Directors of  
Covenant Health:

We have audited the accompanying consolidated financial statements of Covenant Health and its subsidiaries (Covenant) which comprise the consolidated balance sheets as of December 31, 2013 and 2012 and the related consolidated statements of operations and changes in net assets and cash flows for the years then ended, and the related notes to the consolidated financial statements.

### *Management's Responsibility for the Financial Statements*

Management is responsible for the preparation and fair presentation of these consolidated financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

### *Auditor's Responsibility*

Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of Covenant's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

*Opinion*

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Covenant Health as of December 31, 2013 and 2012 and the results of its operations, changes in net assets and cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

*Peering Yearley: Assistant PC*

Knoxville, Tennessee  
April 14, 2014

## COVENANT HEALTH

*Consolidated Balance Sheets*  
(Dollars in Thousands)

	<i>December 31,</i>	
	<i>2013</i>	<i>2012</i>
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 55,399	\$ 36,168
Short-term investments	404	550
Assets limited as to use	23,030	24,568
Patient accounts receivable, less estimated allowances for uncollectible accounts of approximately \$94,300 in 2013 and \$77,900 in 2012	96,912	93,541
Other current assets	44,018	44,341
<b>TOTAL CURRENT ASSETS</b>	<b>219,763</b>	<b>199,168</b>
<b>ASSETS LIMITED AS TO USE, less amounts required to meet current obligations</b>	<b>24,703</b>	<b>41,842</b>
<b>PROPERTY, PLANT AND EQUIPMENT, net of accumulated depreciation and amortization</b>	<b>660,204</b>	<b>683,975</b>
<b>OTHER ASSETS</b>		
Long-term investments	1,007,058	961,990
Bond and note issuance costs, net of accumulated amortization of \$9,455 in 2013 and \$8,333 in 2012	9,933	11,032
Goodwill	8,553	8,553
Other assets	11,158	12,818
<b>TOTAL OTHER ASSETS</b>	<b>1,036,702</b>	<b>994,393</b>
	<b>\$ 1,941,372</b>	<b>\$ 1,919,378</b>

## COVENANT HEALTH

*Consolidated Balance Sheets - Continued*  
*(Dollars in Thousands)*

	<i>December 31,</i>	
	<i>2013</i>	<i>2012</i>
<b>LIABILITIES AND NET ASSETS</b>		
<b>CURRENT LIABILITIES</b>		
Trade accounts payable, accrued expenses and other liabilities	\$ 120,593	\$ 131,132
Accrued salaries, wages, compensated absences and amounts withheld	55,644	51,142
Estimated third-party payer settlements	9,119	12,626
Current portion of long-term debt and capital lease obligations	12,196	21,771
<b>TOTAL CURRENT LIABILITIES</b>	<b>197,552</b>	<b>216,671</b>
<b>LONG-TERM DEBT AND CAPITAL LEASE OBLIGATIONS, less current portion</b>		
	705,260	728,622
<b>OTHER LONG-TERM LIABILITIES</b>	<b>51,799</b>	<b>66,818</b>
<b>TOTAL LIABILITIES</b>	<b>954,611</b>	<b>1,012,111</b>
<b>COMMITMENTS, CONTINGENCIES AND OTHER - Note I</b>		
<b>NET ASSETS</b>		
Unrestricted	977,415	897,789
Temporarily restricted	9,346	9,478
<b>TOTAL NET ASSETS</b>	<b>986,761</b>	<b>907,267</b>
	<b>\$ 1,941,372</b>	<b>\$ 1,919,378</b>

## COVENANT HEALTH

*Consolidated Statements of Operations and Changes in Net Assets*  
*(Dollars in Thousands)*

	<i>Year Ended December 31,</i>	
	<i>2013</i>	<i>2012</i>
Change in unrestricted net assets:		
Unrestricted revenue and support:		
Patient service revenue, net of contractual adjustments and discounts	\$ 1,111,397	\$ 1,088,843
Provision for bad debts	(101,014)	(86,197)
Net patient service revenue	1,010,383	1,002,646
Other operating revenue	63,954	45,917
Net assets released from restrictions used for operations	2,563	2,552
<b>TOTAL REVENUE AND SUPPORT</b>	<b>1,076,900</b>	<b>1,051,115</b>
Expenses:		
Salaries and benefits	513,013	505,955
Supplies and other	465,979	457,576
Provision for depreciation and amortization	70,301	68,477
Interest	14,076	18,730
<b>TOTAL OPERATING EXPENSES</b>	<b>1,063,369</b>	<b>1,050,738</b>
<b>INCOME FROM CONTINUING OPERATIONS</b>	<b>13,531</b>	<b>377</b>
Non-operating gains (losses):		
Investment income	26,977	35,012
Gain (loss) on early extinguishment of debt - Note F	309	(3,242)
<b>NET NON-OPERATING GAINS</b>	<b>27,286</b>	<b>31,770</b>
<b>EXCESS OF REVENUE, GAINS AND SUPPORT OVER EXPENSES AND LOSSES FROM CONTINUING OPERATIONS</b>	<b>40,817</b>	<b>32,147</b>
Additional gain on sale of discontinued operations - Note N	-	14,320
<b>EXCESS OF REVENUE, GAINS AND SUPPORT OVER EXPENSES AND LOSSES</b>	<b>40,817</b>	<b>46,467</b>
Change in net unrealized gains on investments	37,990	36,748
Contributions of property	482	925
Net assets released from restrictions for capital additions	337	271
<b>INCREASE IN UNRESTRICTED NET ASSETS</b>	<b>79,626</b>	<b>84,411</b>

## COVENANT HEALTH

*Consolidated Statements of Operations and Changes in Net Assets - Continued*  
*(Dollars in Thousands)*

	<i>Year Ended December 31,</i>	
	<i>2013</i>	<i>2012</i>
Change in temporarily restricted net assets:		
Restricted gifts and bequests	2,598	3,238
Investment income and realized/unrealized net losses on investments	170	107
Net assets released from restrictions	(2,900)	(2,823)
INCREASE (DECREASE) IN TEMPORARILY RESTRICTED NET ASSETS	(132)	522
INCREASE IN NET ASSETS	79,494	84,933
NET ASSETS, BEGINNING OF YEAR	907,267	822,334
NET ASSETS, END OF YEAR	<u>\$ 986,761</u>	<u>\$ 907,267</u>

## COVENANT HEALTH

*Consolidated Statements of Cash Flows*  
*(Dollars in Thousands)*

	<i>Year Ended December 31,</i>	
	<i>2013</i>	<i>2012</i>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Increase in net assets	\$ 79,494	\$ 84,933
Adjustments to reconcile increase in net assets to net cash provided by operating activities		
Provision for depreciation and amortization	70,301	68,477
Net realized and unrealized gains on investments and assets limited as to use	(44,669)	(53,775)
Discount amortization on capital appreciation bonds	3,190	10,974
Property contributions	(482)	(925)
Restricted contributions	(2,598)	(3,238)
Loss (gain) on early extinguishment of debt	(309)	3,242
Gain on sale of previously discontinued operations	-	(14,320)
Increase (decrease) in cash due to changes in:		
Patient accounts receivable	(3,371)	5,044
Other current assets	323	(218)
Other assets	(1,017)	(2,705)
Trade accounts payable, accrued expenses and other liabilities	(7,673)	4,709
Accrued salaries, wages, compensated absences and amounts withheld	4,502	3,378
Estimated third-party payer settlements	(3,507)	578
Other long-term liabilities	(15,019)	(18,115)
Total adjustments	(329)	3,106
<b>NET CASH PROVIDED BY OPERATING ACTIVITIES</b>	<b>79,165</b>	<b>88,039</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Capital expenditures	(48,988)	(105,454)
Proceeds from sale of property, plant and equipment	376	1,176
Purchases of investments	(170,091)	(231,315)
Proceeds from redemption or maturities of investments	168,634	226,585
Decrease in assets limited as to use	19,881	33,452
Investment in unconsolidated affiliates	-	(159)
Goodwill acquired	-	(6,522)
Distributions from unconsolidated affiliates	2,294	2,250
<b>NET CASH USED IN INVESTING ACTIVITIES</b>		
<b>FROM CONTINUING OPERATIONS</b>	<b>(27,894)</b>	<b>(79,987)</b>



## COVENANT HEALTH

*Consolidated Statements of Cash Flows - Continued*  
*(Dollars in Thousands)*

	<i>Year Ended December 31,</i>	
	<i>2013</i>	<i>2012</i>
Additional gain on sale of discontinued operations	-	15,073
NET CASH USED IN INVESTING ACTIVITIES	(27,894)	(64,914)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of long-term debt	-	160,753
Redemption of debt	(9,691)	(159,636)
Repayment of debt and capital lease obligations	(24,925)	(21,057)
Payment of acquisition and financing costs	(22)	(804)
Proceeds from restricted contributions	2,598	3,238
NET CASH USED IN FINANCING ACTIVITIES	(32,040)	(17,506)
NET INCREASE IN		
CASH AND CASH EQUIVALENTS	19,231	5,619
CASH AND CASH EQUIVALENTS, beginning of year	36,168	30,549
CASH AND CASH EQUIVALENTS, end of year	\$ 55,399	\$ 36,168
SUPPLEMENTAL INFORMATION:		
Cash paid for interest	\$ 9,790	\$ 8,921
Capital additions in accounts payable	\$ 1,859	\$ 4,724
Equipment acquired through capital lease arrangements	\$ -	\$ 1,812

**Attachment C, Orderly Development, 7.c**

**TDH License and TJC Certificate**

# Board for Licensing Health Care Facilities



State of Tennessee

## DEPARTMENT OF HEALTH

0000000073

No. of Beds 0157

*This is to certify, that a license is hereby granted by the State Department of Health to*

*to conduct and maintain a*

MORRISTOWN-HAMBLEN HOSPITAL ASSOCIATION

*Hospital*

MORRISTOWN-HAMBLEN HEALTHCARE SYSTEM

*Located at*

908 WEST FOURTH NORTH STREET, MORRISTOWN

*County of*

HAMBLEN

, Tennessee.

127

*This license shall expire* APRIL 24, 2015, *and is subject*

*to the provisions of Chapter 11, Tennessee Code Annotated. This license shall not be assignable or transferable, and shall be subject to revocation at any time by the State Department of Health, for failure to comply with the laws of the State of Tennessee or the rules and regulations of the State Department of Health issued thereunder.*

*In Witness Whereof, we have hereunto set our hand and seal of the State this* 24TH *day of* APRIL, 2014.

*In the Distinct Category(ies) of:* GENERAL HOSPITAL  
PEDIATRIC GENERAL HOSPITAL



By *James J. Davis, MPH*

DIRECTOR, DIVISION OF HEALTH CARE FACILITIES

By *James J. Davis, MPH*

COMMISSIONER

# Morristown-Hamblen Hospital Association

Morristown, TN

has been Accredited by



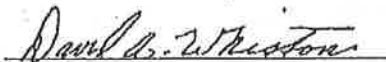
## The Joint Commission

Which has surveyed this organization and found it to meet the requirements for the

### Ambulatory Health Care Accreditation Program

November 3, 2011

Accreditation is customarily valid for up to 36 months.

  
David A. Whiston, D.D.S.  
Chairman of the Board

Organization ID #: 7881  
Print/Reprint Date: 05/14/12

  
Mark Chassin, M.D.  
President

The Joint Commission is an independent, not-for-profit, national body that oversees the safety and quality of health care and other services provided in accredited organizations. Information about accredited organizations may be provided directly to The Joint Commission at 1-800-994-6610. Information regarding accreditation and the accreditation performance of individual organizations can be obtained through The Joint Commission's web site at [www.jointcommission.org](http://www.jointcommission.org).



This reproduction of the original accreditation certificate has been issued for use in regulatory/payer agency verification of accreditation by The Joint Commission. Please consult Quality Check on The Joint Commission's website to confirm the organization's current accreditation status and for a listing of the organization's locations of care.

**Attachment C, Orderly Development, 7.d**

**Inspections & Corrections**



May 8, 2012

Jeremy Biggs  
President/CAO  
Morristown-Hamblen Hospital Association  
908 West Fourth North Street  
Morristown, TN 37814

Joint Commission ID #: 7881  
Program: Hospital Accreditation  
Accreditation Activity: Unannounced  
Accreditation Follow-up  
Accreditation Activity Completed: 05/04/2012

Dear Mr. Biggs:

The Joint Commission would like to thank your organization for participating in the accreditation process. This process is designed to help your organization continuously provide safe, high-quality care, treatment, and services by identifying opportunities for improvement in your processes and helping you follow through on and implement these improvements. We encourage you to use the accreditation process as a continuous standards compliance and operational improvement tool.

The Joint Commission is granting your organization an accreditation decision of Accredited for all services surveyed under the applicable manual(s) noted below:

Comprehensive Accreditation Manual for Hospitals

This accreditation cycle is effective beginning November 04, 2011. The Joint Commission reserves the right to shorten or lengthen the duration of the cycle; however, the certificate and cycle are customarily valid for up to 36 months.

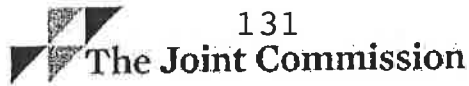
Please visit Quality Check® on The Joint Commission web site for updated information related to your accreditation decision.

We encourage you to share this accreditation decision with your organization's appropriate staff, leadership, and governing body. You may also want to inform the Centers for Medicare and Medicaid Services (CMS), state or regional regulatory services, and the public you serve of your organization's accreditation decision.

Please be assured that The Joint Commission will keep the report confidential, except as required by law. To ensure that The Joint Commission's information about your organization is always accurate and current, our policy requires that you inform us of any changes in the name or ownership of your organization or the health care services you provide.

Sincerely,

Ann Scott Blouin, RN, Ph.D.  
Executive Vice President  
Accreditation and Certification Operations



Morristown-Hamblen Hospital Association  
908 West Fourth North Street  
Morristown, TN 37814

**Organization Identification Number: 7881**

**Program(s)**  
Hospital Accreditation

**Survey Date(s)**  
05/04/2012-05/04/2012

#### **Executive Summary**

**Hospital Accreditation :** As a result of the accreditation activity conducted on the above date(s), there were no Requirements for Improvement identified.

If you have any questions, please do not hesitate to contact your Account Executive.

Thank you for collaborating with The Joint Commission to improve the safety and quality of care provided to patients.





**Attachment**

**Proof of Publication**

**AFFIDAVIT OF PUBLICATION****STATE OF TENNESSEE****COUNTY OF HAMBLLEN**R. Michael Fishman

Printed Name

Personally appeared before the undersigned authority and made oath that he is the Editor and Publisher of the Citizen Tribune and that the attached item was published in said newspaper on the following dates:

10/9/2014.

Signed



Name of Account: Covenant Health/MHHS

Order Number: 22063455

Sworn to, and subscribed before me at Morristown, TN, this 9 th day of October, 2014.



Notary Public

Commission expires: 12/06/2015



## NOTIFICATION OF INTENT TO APPLY FOR A CERTIFICATE OF NEED

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. § 68-11-1601 *et seq.*, and the Rules of the Health Services and Development Agency, that: Morristown-Hamblen Hospital, an Acute Care Hospital owned by Morristown-Hamblen Hospital Association with an ownership type of Not-for-Profit Corporation and to be managed by (Not Applicable), intends to file an application for a Certificate of Need for: the initiation of Mobile Extra-Corporeal Shock Wave Lithotripsy Services using vendor-owned mobile lithotripsy medical equipment for two (2) days per week on the hospital campus at 908 West Fourth North Street in Morristown, Tennessee. The total estimated project cost is \$328,900.

The anticipated date of filing the application is: October 14, 2014.

The contact person for this project is Mike Richardson, Vice President, Strategic Planning & Development who may be reached at: Covenant Health, 280 Fort Sanders West Boulevard, Building 4, Suite 218, Knoxville, Tennessee 37922, 865-531-5123.

Upon written request by interested parties, a local Fact-Finding public hearing shall be conducted. Written requests for hearing should be sent to:

Health Services and Development Agency  
Andrew Jackson Building, 9<sup>th</sup> Floor  
502 Deaderick Street  
Nashville, Tennessee 37243

Pursuant to T.C.A. § 68-11-1607(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

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# SUPPLEMENTAL

**October 24, 2014**

**2:57 pm**

October 22, 2014

Jeff Grimm, HSDA Examiner  
Tennessee Health Services and Development Agency  
Andrew Jackson Building, 9<sup>th</sup> Floor  
502 Deaderick Street  
Nashville, TN 37243

**RE: Certificate of Need Application CN1410-043  
Morristown-Hamblen Hospital – Mobile Lithotripsy CON**

Dear Mr. Grimm:

Please find below our response to the supplemental questions you sent on October 16, 2014 regarding the above-referenced CON application seeking approval to initiate mobile extracorporeal shockwave lithotripsy services (ESWL) for two (2) days per week at Morristown-Hamblen Hospital, 908 West Fourth North Street, Morristown, Tennessee 37814.

Should you have any additional questions or require additional information, please let me know at your earliest convenience.

Sincerely,



Mike Richardson  
Vice President, Strategic Planning and Development  
Covenant Health

Enclosure

---

**1. Section A, Applicant Profile, Item 4, HSDA Equipment Registry, Outstanding CON Status Updates**

The applicant facility's ownership by Covenant Health & listing of affiliated facilities on page 3 is noted. Please affirm that the owner has appropriately registered and reported utilization for same to the HSDA Equipment Registry as required under Agency Statute.

**All Covenant Health affiliates have appropriately registered and reported utilization to the HSDA Equipment Registry as required under Agency Statute. All medical equipment reports for Covenant Health affiliates have been submitted and completed for the 2014 annual update. This was confirmed by Alecia L. Craighead, HSDA Statistical Analyst, on 10/20/14.**

**See Supplemental Attachment: Question 1**

Please identify a brief project update for the status of any outstanding/unimplemented Certificates of Need projects the owner has a financial interest in, such as Roane Medical Center, CN1101-001A. In your response, please include the project expiration date and the date(s) of all Annual Project Reports that apply.

**The Morristown-Hamblen Hospital Fixed PET/CT CON project (CN1009-040) is the only "outstanding" Certificate of Need Project currently for Covenant Health and its affiliates. The most recent Annual Project Report for this project, submitted to the HSDA in July 2014, is included as an attachment. The project is on schedule to be completed prior to the current expiration date of 2/1/2015.**

**The Roane Medical Center Replacement Hospital CON project (CN1101-001) was completed early and under budget. Appropriate documentation was submitted to the HSDA. A copy of both the 2013 Annual Progress Report (5/31/2013) and the 2014 Final Project Report (5/21/2014) are included as attachments. The expiration date for this project was to be 6/1/2015 and the HSDA website reflects that the "status" of this project is "implemented".**

**See Supplemental Attachment: Question 1**

**2. Section A, Applicant Profile, Item 9**

The bed complement data is noted. Review of the 2012 and 2013 JAR revealed that the hospital staffed 149 and 159 licensed beds, respectively, during those periods. The JAR report also reflects a staffed bed occupancy of approximately 49.5% in CY2012 decreasing to 44.2% in CY2013. This chart reflects a current staffed bed level of 151

**October 24, 2014****2:57 pm**

staffed beds. Please briefly describe those key factors that account for increase in staffed beds from CY2012.

**“Staffed beds” within a hospital’s “licensed bed” count change often due to flexible staffing patterns tied to actual patient volumes, efficiency standards, and many other operational considerations. General factors that account for changes in a staffed bed count are primarily related to ongoing operations, minor facility renovations, ongoing clinical unit maintenance and upgrades, physician practice patterns, timing of “staffed bed” documentation, and ongoing patient volume fluctuations in a dynamic healthcare environment. Specific factors related to the noted changes include: 1) the “3 South” nursing unit space (12 beds / 12 rooms) was closed temporarily in October 2012 and reopened in January 2013; and 2) the “3 North” nursing unit underwent renovations in 2013 resulting in a reduction in bed count on the unit (i.e. a decrease of 7 staffed beds).**

Per the applicant’s 2013 JAR, the number of Med/Surg staffed beds appears to exceed the number of licensed beds for the service that are reflected in the JAR and the table provided for this response. Please clarify.

**Page 22 of the Hospital Joint Annual Report (JAR) asks for both 1) “Licensed Adult and Pediatric Beds as of the Last Day of the Reporting Period” and 2) for “The number of adult and pediatric Staffed Beds set up, staffed and in use as of the Last Day of the Reporting Period”. For the most current MHH JAR (2013), those numbers were 167 licensed beds and 159 staffed beds on the last day of the reporting period.**

**Additionally, the chart on page 23 of the Hospital JAR requests documentation of the “Number of Beds Set Up and Staffed on a typical day” for the reporting period. For the most current MHH JAR (2013), MHH reported 159 beds set up and staffed on a typical day.**

**It is worth noting that the allocated JAR chart lines (and parameters) do not exactly match the “Bed Complement Data” chart of the current CON application. MHH is licensed for 167 acute care hospital beds [including approval to operate 6 NICU beds (CN0008-068) and 12 Geriatric Psychiatric beds (CN9701-007)], most of which can be operated to address various and changing inpatient (and medical staff) needs in the community. The individual who completed the chart for the 2013 JAR likely combined some staffed beds in a manner that varied from the more recent chart completed for the current CON application. Regardless, the “total” staffed beds and the staffed “Medical” and “Surgical” beds documented in both the JAR chart and the CON chart do not exceed the total number of licensed beds approved for MHH.**

**A copy of the current licensed bed count information from the Tennessee Department of Health, Health Care Facilities website listing is included for**



reference as an attachment – as well as pages 1-2 and 22-23 of the most recent MHH JAR (2013).

**See Supplemental Attachment: Question 2**

**3. Section A, Applicant Profile, Item 13**

The applicant's gross charges are discussed in detail in other parts of the application. Will professional charges for the ESWL procedures be billed separately by the appropriate physicians or payments made by the hospital in accordance with prior agreements? If by the physicians, please address their participation in Medicare and TennCare such that enrollees can be assured access to services.

**All professional charges for the ESWL procedures will be billed separately by the appropriate physicians. Each of the Urology, Emergency Medicine, and Radiology physicians that will be involved with this project are Medicare and TennCare providers so enrollees can be assured access to the ESWL services provided at MHH. The payer mix for physicians involved with the project will be the same as that outlined for MHH in the CON application.**

**4. Section B, Project Description, Item 1 and Section C, Need, Item 6**

The reference to and documentation of physician support is noted. Please also briefly discuss the clinical leadership planned for the proposed mobile ESWL service and provide a list of active MHH medical staff (with status of board certification) that will be participating in the project.

**Primary clinical leadership for the program will be provided by Dr. Philip Serbin, Urologist (Board Certification: Urology). He will work in collaboration with the Chief of Surgery, Dr. Ronald Christopher, the Chief of Staff, Dr. Shahin Assadnia (Board Certifications: Vascular and General Surgery) and the Emergency Department Director, Dr. Jackie Livesay (Board Certification: Internal Medicine) in the establishment and management of the program.**

**October 24, 2014****2:57 pm**

What are the applicant's expectations of physician referrals by specialty to the proposed ESWL mobile service? Please complete the table below.

Specialty	Physicians practicing in PSA/SSA*	ESWL Referrals Year 1
Family Practice	11	2
Internal Medicine	6	2
OB/GYN	4	1
Orthopedics	5	1
General Surgery	6	2
Urology	4	12
Other**	136	32
<b>TOTAL</b>	<b>172</b>	<b>52</b>

\* Represents the 172 physicians most aligned with MMH via Medical Staff Privileges: Active Privileges (68), Courtesy Privileges (30), and Consulting Privileges (74)

\*\* Includes Emergency Department physicians; most MHH ESWL referrals are expected from patient "self referrals" (i.e. patients who arrive at the MHH Emergency Department seeking care due to acute pain associated with kidney stones) and/or patients who are referred directly to the MHH Emergency Room by another provider. All such patients will be evaluated in the MHH Emergency Department by qualified Emergency Medicine, Radiology, and Urology physicians and staff as appropriate.

#### **5. Section B, Project Description, Item II.A.**

The absence of any need for renovation or construction is noted. Please provide a general description of the operating room (OR#5) to be dedicated to the proposed service (size, location, access by patients, floor, etc.). What attributes does the OR have that account for the decision to dedicate it to use by physicians and their patients for the proposed ESWL service? In your response, please also describe what accommodations are planned for the use of a C-Arm for the mobile unit, if any.

As indicated on the Floor Plan drawings included with the original CON application, MHH Operating Room Five (OR # 5) is located in the Existing Surgery Department of Morristown-Hamblen Hospital which is located on the Second Floor of the Main Hospital Building. Like all of the operating rooms at MHH, OR # 5 will be easily accessible by both inpatients and outpatients who may access the service through the Surgery Department registration/intake area – or even directly from the Emergency Department if needed. As can be seen on the Site Plan drawing included with the original CON application, the MHH Surgery Suite and Emergency Department are in very close proximity to one another on the same side of the main hospital building.

MHH OR # 5 is about 20 ft x 22 ft (approximately 440 total square feet), offering adequate clinical space, appropriate design, and suitable flooring and fixtures for all anticipated lithotripsy procedures. This operating room was selected because it is one of the most suitable areas for the lithotripsy procedures and it offers the most flexible option for ESWL scheduling in a manner that does not disrupt other Surgery Department operations.

**October 24, 2014****2:57 pm**

While OR # 5 will likely be used for all anticipated ESWL cases, the operating room will not be solely dedicated to ESWL procedures. The room is a standard, modern, and fully-equipped general surgery procedure room that can and will be used for other cases as well – and for lithotripsy cases whenever needed. Like all operating procedures scheduled for the MHH Surgery Department, the lithotripsy cases will be scheduled for OR # 5 as appropriate on the master schedule by MHH Surgery Department leadership and physicians.

The Floor Plan drawings actually show the efficient pathway that will be used to move the mobile lithotripsy unit into OR # 5 from the existing service elevator in the Surgery Suite.

MHH physicians and staff will utilize one of the existing C-Arms in the MHH surgery suite as needed in conjunction with the mobile lithotripsy unit.

Since use by outpatients is expected to account for approximately 95% of MHH's projected utilization, how will the proposed area in the hospital be an improvement or enhancement from the current mobile lithotripsy location at Lakeway Regional Hospital?

The proposed area of the MHH ESWL service in the hospital will be similar to that of Lakeway, allowing a similar care environment for the patients and different medical staffs of the two organizations. Sharing the existing equipment within the service area does not take anything away from the services available to patients and physician at Lakeway Regional Hospital. Rather, the project simply enhances access in the community while allowing an underutilized vendor-owned asset to be more frequently used in a manner that allows more patients to receive care in the service area communities where they work and live.

The proposed mobile lithotripsy service will improve access to ESWL services for the entire medical staff of MHH, community physicians in the region, and many patients who seek care and clinical consultation at MHH. MHH provides more inpatient, outpatient, and emergency care to patients who reside in the project service area than any other healthcare provider. Moreover, the proposed area to be used in the MHH Surgery Department is in immediate on-site proximity to the MHH Emergency Department where approximately 300 annual patient encounters related to kidney stones have occurred in recent years.

**6. Section B, Project Description, Item B. II.C. (need for the service)**

The discussion is noted. One key benefit appears to be the use of the service as an alternative to invasive surgeries. Can the applicant offer some insight as to the magnitude of same in the PSA and the potential reduction in surgeries resulting from this project?

**ESWL procedures provide a safe, effective, and less-invasive clinical alternative to surgical procedures for many patients with kidney stones. Therefore, many patients leave the service area for ESWL procedures that typically yield very positive clinical outcomes. While there may be a few patients who could receive an ESWL procedure before other forms of stone retrieval, the applicant does not anticipate a significant reduction in the number of other urological procedures (i.e. which are often a matter of patient preference, clinical practice patterns, etc.).**

Review of HSDA records revealed that approximately 97% residents in the PSA and SSA have used ESWL providers in Knox County for the past 3 years in spite of the presence of the existing 7 day per week mobile service on the Lakeway Regional Hospital campus within 1 mile of the applicant. Given this trend, the need for the project is unclear. Please explain by highlighting what has changed such that the applicant expects to reverse the extensive outmigration of area residents for treatment in other parts of Tennessee?

**Although Lakeway Hospital has approval to operate mobile lithotripsy equipment seven days per week, Lakeway only performed six (6) procedures during the most recent reporting year of the HSDA Equipment Registry and the Tennessee Hospital Joint Annual Report. Several months prior to the filing of this CON application, the CHS/Lakeway leadership team provided written confirmation that they are not opposed to this needed MHH project that will be developed in an orderly manner.**

**Another background consideration is the clinical training, experience, preferences, and practice patterns of various physicians who serve patients in the region. For instance, it is the applicant's current understanding that Lakeway Regional Hospital has at least one urologist on its medical staff that does not often use the lithotripsy equipment to treat his patients. Conversely, MHH has a new urologist (Dr. Serbin) who utilizes ESWL services often as an important clinical tool for treating patients with kidney stones. As indicated within the physician support letters for this project, the new urologist at MHH, the MHH Emergency Department physicians and staff, and the overall MHH Medical Staff would like to have ESWL equipment on site at to care for the significant and growing number of their patients with kidney stones.**

**As outlined on pages 21 and 36 of the original CON application, reversal of a reasonable portion of the documented ESWL outmigration from the project service area will come primarily from patients who have received care from other Covenant Health facilities. If the service is approved for MHH, the applicant believes that a**

significant number of patients who choose Covenant Health for their health care will elect to have their ESWL procedures performed closer to where they work and live. Additionally, increased community awareness about the growing MHH Medical Staff during the next few years and the proposed ESWL service accessibility at MHH may further reduce unnecessary outmigration from the service area.

## **7. Section B, Project Description, Item E.2**

Please also describe the date of manufacture of the unit, its current years in service and expected useful life, and any technological advantages in comparison to other ESWL models.

The following information about the proposed mobile ESWL equipment to be used for the project was supplied by Medispec, Ltd.:

- The Medispec mobile ESWL unit was manufactured in Nov 2011
- The mobile ESWL system was first used at Lakeway Hospital in Nov 2012
- The useful life expectancy of the mobile ESWL system is 10 years
- As for technological advantages, Medispec has the largest "F2" being manufactured today (this is the equivalency of the bulls-eye of a target, i.e. a larger target is easier to hit). Also, the Medispec equipment has one of the "highest bar-pressure" ratings available (this is similar to the engine power of the system). The Medispec "stone free success rate" is one of the highest in the industry (82.9%) – and the Medispec equipment retreatment rate is one of the lowest in the industry (only 6-7%).

**Items (a) and (b):** the responses to these items identify what will amount to a change in the equipment lease arrangement between the equipment vendor and Lakeway Regional for the use of the unit on a full week basis. Since the equipment vendor is the same for both hospitals, what measures may be needed to adjust Lakeway Regional's equipment lease such that the proposed schedule can be honored?

According to Medispec, the equipment vendor used by Lakeway and to be used by MHH, Lakeway Regional Hospital's volume does not necessitate full-time placement of a mobile ESWL unit. Medispec will work with Lakeway Regional Hospital as appropriate to amend their current agreement in an acceptable manner to allow the mobile ESWL unit to be shared with MHH. Furthermore, Medispec will collaborate with each hospital to determine appropriate treatment schedules to ensure operational efficiency and maintain flexibility to optimize patient care as appropriate. Medispec has confirmed their understanding that Lakeway has already agreed to this collaborative arrangement to share the existing mobile ESWL equipment that has been underutilized to address community needs.

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While Lakeway has been approved to use a mobile lithotripsy unit for up to seven (7) days per week, their actual utilization in 2013 was only six (6) ESWL procedures for the entire year. The vendor has provided assurances that they will be able to meet the patient care and physician needs at both hospitals utilizing a shared mobile lithotripsy unit for the foreseeable future – and that they will support the practical logistics and scheduling for a unit to be shared by two hospitals in such close proximity to one another. Furthermore, the equipment lease vendor is also the ESWL equipment manufacturer – and has expressed a commitment to honor both contracts as appropriate, even in the unlikely event that they might need to place another mobile unit in the region at no additional expense to either local hospital.

Based on the projected utilization on page 21 of the application, approximately 1 procedure per week is anticipated in Year 1 increasing to 2 per week in Year 3. In light of same, please describe how the applicant determined an OR was needed a total of 8 hours per week for the mobile service. In your response, please also describe any additional changes that may be required to accommodate the operation of the unit on the days noted without adversely impacting surgeries for other services (orthopedic, general surgery, etc.).

To clarify, although multiple operating rooms in the MHH Surgery Suite could accommodate ESWL cases, OR # 5 will likely be used for all anticipated MHH ESWL procedures – however, OR # 5 does not need to be dedicated to ESWL procedures alone. Like all MHH operating rooms, OR # 5 scheduling capacity will be used only if/when needed. Most ESWL procedures will only take about 45-75 minutes (including room prep and turnaround times) depending upon the size of the kidney stone. Based upon anticipated utilization for years 1-3 of operations, the room would likely be used on average only 1-3 hours per week total for ESWL procedures.

As indicated in the original CON application, a good number of ESWL procedures may be scheduled on Tuesdays and Fridays Noon-5:00 PM if possible – while additional hours and alternative scheduling times can be available to accommodate patient and/or physician needs. From a capacity standpoint, OR # 5 can easily accommodate as many as eight ESWL procedures per day on a standard schedule; however, no more than a few cases would typically be scheduled on any specific day.

MHH does not anticipate any unusual or adverse impact to other operations in the Surgery Department with the initiation of ESWL services. Administrative and physician leadership of the Surgery Department will coordinate room capacity and utilization efficiently to optimize patient care and physician time via existing and effective OR scheduling functions. Furthermore, the needed project has strong demonstrated support from the MHH Medical Staff.

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**Item c – Lease/Contract Cost:** given the vendor quote for equipment payments on a \$1,350 per procedure basis for an initial term of 3 years, what are the arrangements if for some reason no patients need to be treated on a scheduled day of mobile service? Please clarify what costs the hospital will incur if a patient does not give notice and is a no-show, and the unit comes to the hospital to deliver a service.

Beyond the quarterly minimum outlined in the equipment lease agreement, there is no additional charge (or cost) to MHH if the mobile lithotripsy equipment is not used on any specific day. If there is a “patient no show” or “cancellation” (i.e. “no click” or “no procedure”), there is “no fee” paid by MHH. Although a few “patient no shows” might occur, patients with kidney stones are typically very eager for the non-invasive and safe procedure that provides almost immediate relief. Medispec has confirmed their shared understanding of this arrangement.

MHH plans to utilize existing hospital employees to move the ESWL equipment whenever needed (although the vendor is willing to do so if ever needed for a nominal fee). Furthermore, the vendor will work with both MHH and Lakeway Hospital to coordinate logistics related to the ESWL equipment to address both patient and physician needs. Considering the anticipated needs of both MHH and Lakeway Hospital, the mobile lithotripsy equipment will usually sit idle and readily available for use if/when needed or scheduled.

Review of the equipment quote also revealed that the applicant is responsible for a minimum lease payment (9 procedures per quarter); the cost of providing a suitable C-arm to use in conjunction with the unit, and a vendor transportation fee (without C-Arm) of \$300 between Lakeway Regional and the applicant on a prearranged schedule. Given these considerations, what is the applicant’s estimated minimum cost responsibility during the term of the equipment lease? Are the additional costs that are not included in the per click fee lease arrangement reflected in both the Project Costs Chart and the Projected Data Chart? Please clarify.

**All anticipated costs related to the proposed project are included in the Project Costs Chart and the Projected Data Chart:**

- The minimum lease payments outlined in the equipment agreement are significantly lower than the expected cost of utilization projected for years One, Two, and Three of operations as outlined in the original CON application. All anticipated equipment lease payments are included as expenses in the projected data chart.
- MHH plans to utilize one of the existing C-Arms in the Surgery Department when needed for ESWL procedures so no additional cost will be incurred related to this project.
- MHH plans to utilize existing hospital employees to move the ESWL equipment whenever needed in a very cost effective manner – so does not expect to pay any vendor transportation fees. Such time and cost of moving

the equipment by existing hospital employees is included in the wage chart and projected data chart contained in the original CON application.

**8. Section C, Need, Item 1 (State Health Plan)**

Although comment is noted, please provide a response to each of the 5 guiding principles of the State Health Plan. The template can be found in Exhibit 1 at the end of this questionnaire.

**See Supplemental Attachment: Question 8**

**9. Section C, Need, Item 1.a. (Project Specific Criteria-Extra-Corporeal Shock Wave Lithotripsy). Please provide a response for each of the items noted below:**

- a. **Determination of Need in Project Service Area (pages 18-20).** The need estimate for 298 ESWL procedures by area residents in 2017 as developed by the Tennessee Department of Health using 2013 data from the HSDA equipment registry and 2017 population data is noted. Review of the applicant's 2013 JAR revealed that residents of Hawkins County accounted for significantly more inpatient discharges in 2013 and 2012 than residents of Claiborne County. Given this finding and Hawkins County's physical location next to Hamblen County, it is unclear why Hawkins County would not be included in the proposed secondary service area in lieu of Claiborne County. Please explain.

MHH does not expect to receive many ESWL patients from Hawkins County during the first few years of the proposed project. While it is possible that a few patients from Hawkins County might seek care at the MHH Emergency Department for kidney stones during the first few years of the project, the applicant expects that most of those patients will continue to seek care to the northeast of the project service area since most ESWL patients from Hawkins County have received care in the Tri-Cities area of Tennessee historically (i.e. hospitals with ESWL services in Sullivan County, etc.). If any patients from Hawkins County were to seek ESWL care from MHH, they are included in the "Other TN Counties" line (3% of total MHH ESWL cases; part of Tertiary Service Area) of the utilization assumptions outlined on page 36 of the original CON application. Additionally, many patient-directed and physician-directed referrals from the populated areas of Hawkins County have moved northeast historically for tertiary care.

While Claiborne County may not be part of the MHH Primary Service Area (PSA) for many services, it is reasonable to include Claiborne County as part of the Secondary Service Area (SSA) for the proposed MHH ESWL project as outlined in the utilization assumptions on page 36 of the original CON application. To summarize, Claiborne County was included in the proposed MHH ESWL project service area for a few key reasons:



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- Claiborne County Medical Center is the only hospital in Claiborne County and they do not provide ESWL services
- Based upon recent experience by healthcare providers in Claiborne County, the Claiborne Medical Center (CMC) leadership team has confirmed that it anticipates sending at least one or two patients each month to MHH if the ESWL service is approved so patient access within the service area can be expanded
- MHH is easily accessible to many Claiborne County residents via State Highway 25 E, as well as via other travel routes
- Both MHH and CMC are clinically aligned affiliates of Covenant Health – and the medical staffs of both hospitals are collaborating across multiple service lines increasingly to improve patient care, satisfaction, and access

- b. **Minimum Volume Standard (page 21)** - The tables showing the methodology to convert the projected ESWL procedures to a full time measure capable of comparison to the 250 procedures/year standard is noted. As such, the utilization in Year 1 is approximately 73% of the standard increasing to 110% of the standard in Year 2. Is this consistent with the applicant's projections in the manner described?

Yes.

- c. **Current Service Area Utilization and Adverse Impact on Existing Providers (pages 22 and 23)** – in light of the discussion with Lakeway Hospital management, did discussion arise about cooperative efforts needed to reverse the trend of outmigration by residents from the service area success that the proposed mobile ESWL service might be successful? What, if any, consideration was given to the development of a working agreement, joint venture or other similar activity to assure success of the service and prevent the potential closure of the Lakeway Hospital mobile service?

Discussion about cooperative efforts by competing hospitals to reverse the trend of outmigration of residents from the service area did not occur. Rather, MHH leadership simply explained their real and growing need to have access to a mobile ESWL unit on site for a couple days each week so members of the MHH medical staff could better care for their patients. CHS/Lakeway leadership understood the situation and confirmed that they are not opposed to MHH having access to mobile ESWL equipment to care for its patients.

Perhaps more importantly, this proposed project represents a unique opportunity for competing hospitals to share an existing medical resource that is operational and underutilized in the service area to meet community needs. As outlined elsewhere in the original CON application and supplemental materials, the commitments and flexibility of a trusted ESWL vendor have created a platform that will allow a working arrangement that will help assure the success of the ESWL service for both hospitals located in very close proximity within Morristown, Tennessee. Any ESWL procedure volumes realized by MHH and/or Lakeway will benefit the equipment vendor organization to be used by both

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hospitals, thus strengthening the company's operational viability in the region in a manner that will help ensure their ongoing commitment to both providers who care for patients in the service area.

Referrals to ESWL service locations are often based upon individual urology physician preferences and practice patterns, medical staff privileges and related call obligations, historical referral relationships, and overall clinical alignment. Additionally, it is very common for physicians to care for patients at the primary campus at which they practice whenever possible – and/or to make tertiary referrals to clinically aligned providers as appropriate to optimize patient care quality, efficiency, and satisfaction. The proposed ESWL equipment-sharing arrangement should support the patient care operations and medical staff needs of both hospitals for the foreseeable future.

Attachment C.1.a.3 was provided showing Service Area Patient Destinations in 2013. It would be helpful to identify the most recent 3 year trend for purposes of this response and, in large part, as a basis for supporting the projected utilization of the service. Please complete the table below (*note: HSDA staff has entered amounts for 2013 for ease of reference*).

	2011	2012	2013	% Change '11-'13
Total # resident ESWL procedures	252	268	293	+16.3%
# residents using Knox Co. Providers	234	261	282	+20.5%
% Residents using Knox Co. providers	93%	97%	96%	+3%
Total ESWL procedures of Knox Co. providers	1,536	1,490	1,592	+3.6%
% Knox Co. provider reliance on PSA/SSA residents	15%	18%	18%	+3%

**Adequate Staffing and Services (page 24)** – please identify the names of all radiologists on the hospital’s medical staff that apply (with copy of CV, if possible). Please identify all referral urological physicians in the service area (PSA/SSA) that apply with name, address and status of medical staff privileges and board certification.

**See Supplemental Attachment: Question 9**

- d. **Transfer and/or Affiliation Agreements (page 26)** – Given the applicant does not meet the Level I Trauma designation; it appears that the applicant’s current agreement for transfer of hospital patients with UT Medical Center will meet this criterion. Will the agreement extend to transfer for patients of the proposed mobile ESWL service?

**Yes, the transfer agreement with UT Medical Center will meet this criterion since that hospital has a Level I Trauma designation. Additionally, patients can be transferred to other tertiary medical centers Tennessee as appropriate.**

- e. **Access, Item a (pages 26 and 27)** – the medically underserved area status of the proposed ESWL primary and secondary service area may warrant consideration given the significant outmigration to other areas of the state for this service. Please identify the MUA status of the counties in the applicant’s proposed service area.

**According to the Tennessee Department of Health Website, each county of the proposed MHH ESWL project service area is considered a “Medically Underserved Areas” (MUA) – and therefore may warrant special consideration considering the significant outmigration to other areas of the state for this service:**

**Cocke:**            *Whole County MUA “Health Professional Shortage Area” (May 2014)*

**Claiborne:**    *Whole County MUA “Health Professional Shortage Area” (May 2014)*

**Grainger:**     *Whole County MUA “Health Professional Shortage Area” (May 2014)*

**Hamblen:**     *Partial County MUA “Health Professional Shortage Area” (May 2014)*

**Jefferson:**    *Partial County MUA “Health Professional Shortage Area” (May 2014)*

*Source: <http://health.state.tn.us/rural/hpsa.html>*

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- f. **Access, Item b** - review of HSDA records revealed that the CY2013 use rate per 1,000 population was higher in only 1 county of the service area (Jefferson County) than the statewide average of 1.7 per 1,000 population. What does this suggest about the need for the project in addition to the comments provided?

In your response, please contact Alecia Craighead, Stat III, HSDA, for additional assistance in completing the table below:

**ESWL Use Rates by County per 1,000 Population in Applicant's Service Area**

County	2011	2012	2013
Cocke	1.38	1.22	1.40
Claiborne	1.34	1.27	1.05
Grainger	1.89	1.44	1.48
Hamblen	0.84	1.07	1.26
Jefferson	1.24	1.57	1.77
<b>Statewide</b>	<b>1.2</b>	<b>1.1</b>	<b>1.7</b>

*Sources: Medical Equipment Registry - 8/4/2014 (provided by Alecia Craighead, HSDA) and Tennessee Population 2010-2020 (<http://health.state.tn.us/statistics/quickfacts.htm>). Values calculated by dividing the number of procedures performed on patients originating from a given county by the population estimate for the county for the same year.*

The ESWL "Use Rates" by County and for Tennessee above seem to indicate a few issues:

- For unknown reasons, Tennessee Statewide utilization of ESWL services has increased dramatically from 2012 to 2013 (i.e. 55% reported increase in just one year if the data is accurate).
- All but one county in the MHH ESWL project service area shows growth in ESWL use rates from 2012 to 2013.
- In 2011, all but one county in the MHH ESWL project service area showed significantly higher ESWL use per 1,000 than for Tennessee Statewide.
- In 2012, all but one county in the MHH ESWL project service area showed significantly higher ESWL use per 1,000 than for Tennessee Statewide.
- In 2013, only one county in the MHH ESWL project service area showed significantly higher ESWL use per 1,000 than for Tennessee Statewide. However, if the calculated 2013 Tennessee Statewide ESWL use rate were more similar to 2011 and 2012 rates, every county in the MHH ESWL project service area would exceed the Tennessee Statewide use rate.

In addition to the fact that a majority of the MHH ESWL project service area has demonstrated a higher ESWL use rate than Tennessee Statewide for much of the past three years, the applicant believes that other key facts and utilization assumptions outlined throughout the original CON application indicate that the project is needed – and that projections are both reasonable and conservative.

- g. **Access, Item b** - the applicant states that MHH medical staff witnessed approximately 300 encounters related to kidney stones in the ED and office settings in recent years, with up to 50% that could be candidates for lithotripsy procedures.

HSDA records reflect that few residents of the PSA/SSA used Lakeway Regional's mobile ESWL service in recent years - only 48 patients were treated at Lakeway compared to 540 residents that used Knox County providers in 2012 and 2013. As such, it appears that the need for ESWL services has historically been met by Knox County providers in spite of the availability of the service at Lakeway. Other than eliminating drive times, it is unclear what MHH plans to do to meet area need for the service. Please explain.

Most kidney stone patients who seek ESWL services originate in a hospital's emergency department. Until Dr. Serbin arrived in Morristown in early 2014 to establish his urology practice, a majority of ESWL patients from the MHH Emergency Department went to other hospitals in East Tennessee with established programs and accessible physicians who perform ESWL procedures.

Now that MHH Emergency Department physicians, staff, and patients have access to a local urology physician on the MHH Medical Staff who utilizes ESWL procedures to treat kidney stone patients, many service area patients who seek care at MHH (or with Covenant Health's aligned physicians) will likely choose to receive the needed procedure closer to home with their physician and/or hospital of choice if the needed ESWL service is approved. Approval of the proposed ESWL service will enhance the array of clinical tools available for the MHH Medical Staff on site – and enable a significant number of kidney stone patients who seek care from Covenant Health to have the procedure performed at MHH. This project seeks to utilize an existing medical resource in the service area in a manner that is orderly, efficient, and collaborative – and that enhances patient access, choice, and convenience.

#### **10. Section C, Need, Items 3 and 4 (Service Area)**

**Item 3** - the service area is noted. Please also comment on the rationale for excluding Hawkins County from the applicant's proposed ESWL secondary service area instead of Claiborne County.

MHH does not expect to receive many ESWL patients from Hawkins County during the first few years of the proposed project. While it is possible that a few patients from Hawkins County might seek care at the MHH Emergency Department for kidney stones during the first few years of the project, the applicant expects that most of those patients will continue to seek care to the northeast of the project service area since most ESWL patients from Hawkins County have received care in the Tri-Cities area of Tennessee historically (i.e. hospitals with ESWL services in Sullivan County, etc.). If any patients from Hawkins County were to seek ESWL care from MHH, they are included in the "Other TN Counties" line (3% of total MHH ESWL cases; part of Tertiary Service Area) of the utilization assumptions outlined on page 36 of the original CON application. Additionally, many patient-directed and physician-directed referrals from the populated areas of Hawkins County have moved northeast historically for tertiary care.

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While Claiborne County may not be part of the MHH Primary Service Area (PSA) for many services, it is reasonable to include Claiborne County as part of the Secondary Service Area (SSA) for the proposed MHH ESWL project as outlined in the utilization assumptions on page 36 of the original CON application. To summarize, Claiborne County was included in the proposed MHH ESWL project service area for a few key reasons:

- Claiborne County Medical Center is the only hospital in Claiborne County and they do not provide ESWL services
- Based upon recent experience by healthcare providers in Claiborne County, the Claiborne Medical Center (CMC) leadership team has confirmed that it anticipates sending at least one or two patients each month to MHH if the ESWL service is approved so patient access within the service area can be expanded
- MHH is easily accessible to many Claiborne County residents via State Highway 25 E, as well as via other accessible travel routes
- Both MHH and CMC are clinically aligned affiliates of Covenant Health – and the medical staffs of both hospitals are collaborating across multiple service lines increasingly to improve patient care, satisfaction, and access

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**Item 4** - Please condense information provided in the response by completing the following table using data from the Department of Health website, Certificate of Need enrollee data from the Bureau of TennCare, and demographic information from the US Census Bureau:

	Cocke	Claiborne	Grainger	Grundy	Hamblen	Jefferson	Service Area Total	Tennessee
<b>Current Year 2014, Age 65+</b>	6,669	5,880	4,204	N/A	11,269	9,972	37,994	981,984
<b>Projected Year 2018, Age 65+</b>	6,871	6,378	4,557	N/A	12,067	11,291	41,164	1,102,413
<b>Age 65+, % Change</b>	3.0%	8.5%	8.4%	N/A	7.1%	13.2%	8.3%	12.3%
<b>Age 65+, % Total</b>	18.1%	18.0%	18.2%	N/A	17.6%	18.6%	18.1%	14.9%
<b>2014 Total Population</b>	36,762	32,604	23,111	N/A	64,108	53,729	210,314	6,588,698
<b>2018, Total Population</b>	38,615	33,280	23,675	N/A	65,570	56,872	218,012	6,833,509
<b>Total Pop. % Change</b>	5.0%	2.1%	2.4%	N/A	2.3%	5.8%	3.7%	3.7%
<b>TennCare Enrollees</b>	10,184	8,121	5,118	N/A	13,519	10,568	47,510	1,241,028
<b>TennCare Enrollees as a % of Total Population</b>	27.7%	24.9%	22.1%	N/A	21.1%	19.7%	22.6%	18.8%
<b>Median Age</b>	42.9	41.1	42.1	N/A	39.6	40.8	41.0	38.0
<b>Median Household Income</b>	\$29,764	\$33,568	\$33,185	N/A	\$39,316	\$38,800	\$35,950	\$44,140
<b>Population % Below Poverty Level</b>	26.00%	23.00%	20.20%	N/A	18.60%	19.20%	20.90%	17.30%

**11. Section C, Need, Item 5**

The information provided for Lakeway Hospital, the only ESWL provider in the service area, is noted. However, as noted by the data regarding the high outmigration to Knox County, please also include utilization for the Knox County providers that you identified in Attachment C.1.a.3 for the most recent 3 year period. A suggested template is provided in the table below.

**ESWL Providers; Travel Distances/Times; and Total ESWL Procedures**

<b>Knox County ESWL Provider</b>	<b>Distance from MHH*</b>	<b>2011 procedures</b>	<b>2012 procedures</b>	<b>2013 procedures</b>
Fort Sanders Regional	49.9 miles (55-60 minutes)	182	145	165
North Knoxville	56.0 miles (60-65 minutes)	201	280	351
Parkwest	59.8 miles (63-68 minutes)	511	441	443
Physicians Regional	48.7 miles (53-58 minutes)	103	99	72
Turkey Creek	62.6 miles (67-72 minutes)	0	0	65
UT Medical Center	52.2 miles (55-60 minutes)	539	525	499

*\*note: please show in miles & estimated driving time*

**12. Section C, Need, Item 6**

The projected utilization with breakout by county of patient origin is noted. Given the projected Medicare/TennCare payor mix on page 45, please expand to show all payor sources that account for the applicant's projected gross operating revenue in Year 1 of the project.

Medicare	57 %
Managed Care	21 %
TennCare	15 %
Self Pay	7 %

**13. Section C, Economic Feasibility, Item 1 (Project Cost Chart)**

The chart is noted. Given the acquisition of the ESWL equipment by lease arrangement, the estimated cost should be noted in Section B, line 4 of the chart. Please submit a replacement page with a revised Project Cost Chart.

**See Supplemental Attachment: Question 13**



**October 24, 2014****2:57 pm****14. Section C, Economic Feasibility, Item 4 (Historical and Projected Data Charts)**

**General** - the HSDA is now using a more detailed chart showing a breakout of other expenses. Please revise the charts & submit as replacement pages using the template provided in Exhibit 2 at the end of this questionnaire.

**Exhibit 2:****HISTORICAL DATA CHART-OTHER EXPENSES**

<b><u>OTHER EXPENSES CATEGORIES</u></b>	<b>Year 2011</b>	<b>Year 2012</b>	<b>Year 2013</b>
1. Benefits	6,122,737	6,467,888	5,081,545
2. Management Fees	2,450,000	3,876,179	4,154,126
3. Maintenance	2,612,335	2,317,557	2,048,630
4. Energy , Water & Telephone	1,629,794	1,696,544	1,547,585
5. Professional Services & Insurance	7,653,297	7,388,130	6,542,444
6. Equipment Leases	1,000,078	639,540	809,624
7. Other Expense	1,015,515	1,055,631	3,000,089*
<b>Total Other Expenses</b>	<b>\$22,483,756</b>	<b>\$23,441,469</b>	<b>\$23,184,043</b>

\* HiTech/Meaningful use revenue of \$1,009,000 included

**PROJECTED DATA CHART-OTHER EXPENSES**

<b><u>OTHER EXPENSES CATEGORIES</u></b>	<b>Year_1__</b>	<b>Year_2__</b>
1. Radiology, Lab and Anesthesia	\$ 6,604	\$ 9,906
2. PACU & OR	57,200	85,800
3. Equipment Lease	70,200	105,300
4.	_____	_____
5.	_____	_____
6.	_____	_____
7.	_____	_____
<b>Total Other Expenses</b>	<b>\$134,004</b>	<b>\$201,006</b>

**See Supplemental Attachment: Question 14**

**Historical Data Chart** - the entry for charity and bad debt for the 2013 period is \$24,687,072. Review of the 2013 JAR revealed approximately \$3.1 million in charity and \$12.1 million in bad debt for a combined total of \$15.2 million. What accounts for the difference of approximately \$9.5 million between the chart and the schedule in the JAR? Please clarify.

**Instructions for the Hospital JAR** specify that only actual charity and bad debt be reported. However, the MHH Operating Statements used to complete the Historical Data Chart for the original CON application include an estimated reserve on uncollected revenue, a common financial accounting practice consistent with GAAP.

**Projected Data Chart** – Using the applicant’s staffing pattern and planned wages for the proposed mobile service provided on page 49 (2 FTEs to support the project), it appears that the estimated cost for base salaries is approximately \$79,540 in Year 1 compared to the \$8,164 noted for Line D.1 of the chart. If the higher amount applies, the projected net income in the chart is overstated for both Year 1 and Year 2. Please clarify.

To clarify, the *Staffing Pattern and Wage Comparison* chart on page 49 of the original CON applications shows that each of the employee types involved with the proposed ESWL project will be “less than .05 FTE” (i.e. less than 5% of a Full-Time Equivalent Employee, which is typically 2080 standard hours annually).

Line D.1 of the Projected Data Chart is correct on page 42 of the original CON application:

*Staff Salaries and Wages for Year 1 = \$ 8,164*

*Staff Salaries and Wages for Year 2 = \$ 12,246*

**15. Section C, Economic Feasibility, Items 6A and 6 B**

Item 6A – the average gross charge is noted. Please also identify the charge or fee schedule by procedure classification that the applicant intends to use for the proposed service.

The Service Item Charge Code (procedure classification) is 650011005 for the ESWL procedures to be performed at MHH. The related charge/fee schedule for these procedures is \$9,725. This charge is appropriate for all proposed procedures to be performed at MHH if the project is approved.

Item 6B- the comparison to other provider gross charges and to Medicare allowable charges is noted. Please also include a comparison to the HSDA 1<sup>st</sup>, median and 3<sup>rd</sup> quartile charges available on the HSDA website.

Provided immediately below is the HSDA 1<sup>st</sup> Quartile, Median, and 3<sup>rd</sup> Quartile Charges for ESWL services available on the HSDA website:

Equipment Type	1 <sup>st</sup> Quartile	Median	3 <sup>rd</sup> Quartile
Lithotripter	\$ 9,029.86	\$ 12,783.82	\$ 17,953.48

Source: HSDA Medical Equipment Registry, 09/05/2014

In comparison, the “average gross charge” per lithotripsy procedure when the new MHH mobile service begins is estimated to be \$14,988 – with average deduction from operating revenue estimated at \$11,160 and average “net charge” (or net revenue) estimated at \$3,828. These estimates for the proposed project are consistent with the current charges of Covenant Health for its existing mobile lithotripsy services prior to the filing of this CON application.

Currently, the Medicare allowable fees for lithotripsy procedures at community hospitals like MHH are \$ 2,483.55 - \$ 8,333.55:

- Inpatient - \$2,483.55
- Outpatient - without complications \$5,875.84
- Outpatient - with complications \$8,222.55

Additionally, the proposed charges for the MHH project seem reasonable considering data available about lithotripsy procedures at other approved ESWL sites in Tennessee.

<u>HSDA Approved Lithotripsy Service</u>	<u>Estimated Average Gross Charge</u>
Lakeway Hospital (2013)	\$ 32,456
University Medical Center (2013)	\$ 31,585
Indian Path Medical Center (2013)	\$ 18,186
Physicians Regional Medical Center (2013)	\$ 17,842

Source: Tennessee HSDA Equipment Registry (August 2014)

**16. Section C, Economic Feasibility, Item 9**

The projected Medicare and TennCare payor mix based on gross operating revenues for the 1<sup>st</sup> year of operation is noted. Based on review of the payor mix of Lakeway Regional noted from HSDA records in Attachment C.1.a.3, the applicant's mix varies significantly for Medicare and TennCare as reflected in the table below.

<b>Payor</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>
Medicare	17%	17%	33%
TennCare	17%	23%	34%

Given the proximity to Lakeway, what accounts for the difference in the applicant's projected government payor mix?

**Anticipated payer mix for the MHH ESWL project is consistent with the historical payer mix experienced by MHH for hospital services – and is consistent with the experience of other Covenant Health affiliates who provide ESWL services.**

**Apparent variation is likely due to the nature of small sample sizes since the limited payer mix percentages for Lakeway in the chart above are for Lakeway's ESWL services only – which represents a relatively small number of cases considering that only 6 procedures were performed in 2013; only 42 procedures were performed in 2012; and only 18 procedures were performed in 2011.**

**17. Section C, Orderly Development, Item 3**

As noted in question 13 pertaining to the Projected Data Chart, the table appears to indicate the amount of time and estimated cost for 4 position classifications (2 full time equivalents) that will be dedicated to the proposed mobile ESWL service. The estimated base salary and wages for same is approximately \$79,540 in Year 1 which differs from the cost in the Projected Data Chart on page 42. Please clarify. If in error, please revise the table for this response to correspond with the salary costs in the Projected Data Chart for the proposed service.

To clarify, the *Staffing Pattern and Wage Comparison* chart on page 49 of the original CON applications shows that each of the employee types involved with the proposed ESWL project will be "less than .05 FTE" (i.e. less than 5% of a Full-Time Equivalent Employee, which is typically 2080 standard hours annually).

Line D.1 of the Projected Data Chart is correct on page 42 of the original CON application:

*Staff Salaries and Wages for Year 1 = \$ 8,164*  
*Staff Salaries and Wages for Year 2 = \$ 12,246*

**18. Section C, Orderly Development, Item 7.b.**

Based on the information provided, was the applicant awarded both Joint Commission ambulatory health care accreditation and Joint Commission hospital accreditation effective November 3, 2011? Please clarify.

**Yes. MHH has been awarded both The Joint Commission ambulatory health care accreditation and The Joint Commission hospital accreditation.**

**The proposed ESWL service will be a hospital-based service accessible to the inpatients, outpatients, and emergency department patients served by MHH.**

**Additional documentation regarding the most recent MHH ambulatory health care accreditation by The Joint Commission is provided as a supplemental attachment.**

**See Supplemental Attachment: Question 18**

**October 24, 2014****2:57 pm**

.....

**See Supplemental Attachment: Affidavit**

**SUPPLEMENTAL ATTACHMENTS**

**Question 1**



**October 24, 2014****2:57 pm****Richardson, Mike D**

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**From:** Alecia L. Craighead <Alecia.L.Craighead@tn.gov>  
**Sent:** Monday, October 20, 2014 5:04 PM  
**To:** Richardson, Mike D  
**Subject:** Medical Equipment Status

Mr. Richardson,

At this time, all medical equipment reports for Covenant Health facilities have been submitted and completed for the 2014 annual update.

Thank you.

Alecia L. Craighead  
Statistical Analyst  
Health Services and Development Agency  
Andrew Jackson Building, 9<sup>th</sup> Floor  
502 Deaderick Street  
Nashville, TN 37243  
Office: 615.253.2782  
Fax: 615.741.9884  
[alecia.l.craighead@tn.gov](mailto:alecia.l.craighead@tn.gov)

**October 24, 2014****2:57 pm**

**State of Tennessee  
Health Services and Development Agency**

Andrew Jackson Building, 9<sup>th</sup> Floor

502 Deaderick Street

Nashville, TN 37243

[www.tn.gov/hsda](http://www.tn.gov/hsda)

Phone: 615-741-2364

Fax: 615-741-9884

**ANNUAL PROGRESS REPORT**  
**ANNUAL REVIEW FOLLOWING CERTIFICATION**

Project Name: Morristown-Hamblen Hospital PET/CT Certificate of Need #: CN1009-040

Legal Owner: Covenant Health Approval Date: December 15, 2010

**Project Description:**

Background: HSDA approved the MHH application to replace and upgrade its PET/CT service to fixed PET/CT unit on December 15, 2010. Unforeseen project delays occurred due to the space initially designated for the equipment was not suitable to hold the significant weight of the new equipment. As a result, an alternate site was chosen for PET/CT location and in November 2013, HSDA granted a 6-month extension for our project. Finally, a second 6-month extension was requested by MHH and granted by HSDA in May 2014.

Project Status: 1) Equipment was purchased from Siemens on October 4, 2013. The scheduled delivery date of the equipment is October 29, 2014. Upon equipment arrival, Siemens engineering staff will be on site to begin the two-week installation process at that time. 2) PET/CT space demolition is 100% complete. 3) PET/CT space construction renovation is currently at about 30% completion. 4) Staff has been hired for the PET/CT service line. 5) Staff Training is scheduled and will coincide with the equipment installation beginning on October 29, 2014.

**\*\*\*\*PLEASE SUBMIT EVIDENCE TO SUPPORT EACH ANSWER\*\*\*\***

In a brief narrative, please describe the current stage of completion for the project (use another sheet of paper if necessary). Please note that this report will not be considered complete without this information.

**A. CONSTRUCTION PROJECTS**

1. Anticipated date of project completion. October 27, 2014
2. Provide written confirmation from the contractor documenting the stage of construction at the current time.
3. If proposed construction costs have increased over ten (10%) percent please provide information as an attachment to this form. Please note that such an overrun could require additional action before the Agency.

**B. NON-CONSTRUCTION PROJECTS**

1. Anticipated date of service implementation, acquisition or operation of the facility or equipment as certified.  
November 10, 2014
2. Provide written confirmation from the institutional representative verifying the occupancy/opening date for the service, equipment, or facility.

*[Signature]*

Signature of Authorized Agent or Chief Operating Officer

7/29/14

Date

**October 24, 2014****2:57 pm****Dixon, Brandon**

---

**From:** Dixon, Brandon  
**Sent:** Wednesday, May 21, 2014 5:00 PM  
**To:** 'Mark.Ausbrooks@tn.gov'  
**Cc:** Richardson, Mike D  
**Subject:** FW: Roane Medical Center CN1101-001A  
**Attachments:** Final Progress Report.pdf; Annual Progress Report 5-31-13.pdf

Mr. Ausbrooks,

Attached you will find the requested Final Project Report for Covenant Health's Roane Medical Center project. The original copy was mailed today and you can probably expect it by Monday 5/26.

For reference, I have also included the Annual Progress Report that was previously requested and sent in on 5-31-13.

Let me know if you have any questions. Thank you,

**BRANDON DIXON**

*Covenant Health Properties  
(865) 531-5279 - Office*

---

**From:** Richardson, Mike D  
**Sent:** Wednesday, May 21, 2014 4:51 PM  
**To:** Dixon, Brandon  
**Subject:** FW: Roane Medical Center CN1101-001A

Contact information for Mark Ausbrooks at HSDA office

---

**From:** Mark Ausbrooks [<mailto:Mark.Ausbrooks@tn.gov>]  
**Sent:** Tuesday, May 06, 2014 11:17 AM  
**To:** Richardson, Mike D  
**Subject:** Roane Medical Center CN1101-001A

**This project's Annual Progress Report is due on May 31, 2014. Please complete the attached form and submit to my attention by the due date.**

Pursuant to Public Acts 2002, Chapter No. 780, § 16-11-1609(d): The Health Services and Development Agency Rules require that an Annual Progress Report be submitted each year until the completion/implementation of the project at which time the Final Project Report is due within 90 days of completion/implementation.

**Your attention to this request is appreciated.**

Mark Ausbrooks  
Administrative Assistant  
Health Services & Development Agency  
(615)-253-1455 (direct line)  
(615) 741-2364 (front office)  
(615) 741-9884 (fax)

**October 24, 2014****2:57 pm**

**State of Tennessee**  
**Health Services and Development Agency**

Andrew Jackson Building, 9<sup>th</sup> Floor

502 Deaderick Street

Nashville, TN 37243

[www.tn.gov/hsda](http://www.tn.gov/hsda)

Phone: 615-741-2364

Fax: 615-741-9884

**FINAL PROJECT REPORT**

Please TYPE or PRINT legibly.

Certificate of Need No. CN1101-001AProject Name: ROANE MEDICAL CENTEROwner: COVENANT HEALTHContact: GAYE JOLLY, CAODescription: REPLACEMENT HOSPITAL FOR ROANE COUNTY, TENNESSEE.

Total Bed Complement Before Addition  
 Total Bed Complement

10554

What was the Final Completion Date (opened for public use)?

February 15, 2013

Was the project completed as certified?

☒ YES☐ NO

(If not, describe any changes, deletions, and/or additions on additional sheets.)

**COST FACTORS**

	Original Cost Projection	Final Project Cost
<b>A. Construction and equipment acquired by purchase:</b>		
1. Architectural and Engineering Fees	<u>3,160,645</u>	<u>2,964,540</u>
2. Legal, Administrative (Excluding CON Filing Fee), Consultant Fees	<u>85,000</u>	<u>131,453</u>
3. Acquisition of Site	<u>2,208,920</u>	<u>4,316,330</u>
4. Preparation of Site	<u>7,500,000</u>	<u>5,654,839</u>
5. Construction Costs	<u>36,425,000</u>	<u>35,710,086</u>
6. Contingency Fund	<u>3,402,301</u>	<u>0</u>
7. Fixed Equipment (Not included in Construction Contract)	<u>5,575,000</u>	<u>8,935,167</u>
8. Moveable Equipment (List all equipment over \$50,000)	<u>4,377,108</u>	<u>1,404,740</u>
9. Other (Specify) <u>IT, SIGNAGE, GRAPHICS, PERMITS, TESTING, CONSULT FEES, ETC.</u>	<u>9,221,026</u>	<u>8,225,945</u>
<b>Subtotal</b>	<u>71,955,000</u>	<u>67,343,100</u>
<b>B. Acquisition by gift, donation, or lease:</b>		
1. Facility (inclusive of building and land)	<u>0</u>	<u>0</u>
2. Building only	<u>0</u>	<u>0</u>
3. Land only	<u>0</u>	<u>0</u>
4. Equipment (Specify) _____	<u>0</u>	<u>0</u>
5. Other (Specify) _____	<u>0</u>	<u>0</u>
<b>Subtotal</b>	<u>0</u>	<u>0</u>
<b>C. Financing Costs and Fees:</b>		
1. Interim Financing	<u>0</u>	<u>0</u>
2. Underwriting Costs	<u>0</u>	<u>0</u>
3. Reserve for One Year's Debt Service	<u>0</u>	<u>0</u>
4. Other (Specify) _____	<u>0</u>	<u>0</u>
<b>Subtotal</b>	<u>0</u>	<u>0</u>

**October 24, 2014****2:57 pm**

D.	Estimated Project Cost (A+B+C)	71,955,000	67,343,100
E.	CON Filing Fee	45,000	45,000
F.	<u>Total Estimated Project Cost (D+E)</u>	<u>72,000,000</u>	<u>67,388,100</u>

FINAL COST† \$ 67,343,100FINAL FILING FEE‡ \$ 45,000

If the final project cost is an overrun of the estimated project cost, describe in detail all increases in final costs from those originally projected.

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The Final Filing Fee to be assessed on any cost overrun is to be computed at the rate current at the time the project was certified. Below is the outline of the rates from January 1994 through the present.

PERIOD	FEE PER \$1,000	PREMIUM PREMIUM	FINAL FILING FEE
January 30, 1994 through Present	\$2.25/\$1,000	\$3,000--\$45,000	\$2.25/\$1,000 Total filing fee (initial plus final) not to exceed \$45,000.

I hereby certify that this information is true to the best of my knowledge, information, and belief, and that supplemental written notification will be filed with the Tennessee Health Services and Development Agency in the event of any change in the information given in this report.

*Ray Jolly*  
Chief Operating Officer

5/21/14  
Date

# Roane Medical Center

**SUPPLEMENTAL #1****October 24, 2014****2:57 pm**8045 Roane Medical Center Drive  
Harriman, TN 37748

(865) 316-1000

[www.roanemedical.com](http://www.roanemedical.com)

May 31, 2013

Melissa Bobbitt, ASA 3  
Health Services & Development Agency  
Frost Building, 3<sup>rd</sup> Floor  
161 Rosa L. Parks Blvd.  
Nashville, TN 37243

Dear Ms. Bobbitt,

Please find attached the Annual Progress Report for the Roane Medical Center replacement hospital. Also attached is a schedule confirmation letter from Rentenbach Constructors as well as a project photograph.

We did move into and occupy our facility on February 17, 2013, as scheduled.

I can be reached at (865) 316-2001 should you need additional information.

Sincerely,



Gaye G. Jolly  
President/Chief Administrative Officer

CC: Danny Edsell  
Mike Richardson  
Brandon Dixon

October 24, 2014

2:57 pm



**STATE OF TENNESSEE  
HEALTH SERVICES AND DEVELOPMENT AGENCY**

Frost Building, 3<sup>rd</sup> Floor  
161 Rosa L. Parks Blvd.  
Nashville, TN 37243  
615/741-2364

**ANNUAL PROGRESS REPORT  
ANNUAL REVIEW FOLLOWING CERTIFICATION**

Project Name: Roane Medical Center Certificate of Need #: CN1101-001A

Legal Owner: Covenant Health Approval Date: 4-27-2011

Expiration Date: 4-27-2015

Project Description:

The Attachment A

**\*\*\*\*PLEASE SUBMIT EVIDENCE TO SUPPORT EACH ANSWER\*\*\*\***

In a brief narrative, please describe the current stage of completion for the project (use another sheet of paper if necessary). Please note that this report will not be considered complete without this information.

**A. CONSTRUCTION PROJECTS**

1. Anticipated date of project completion. 12-31-2012
2. Provide written confirmation from the contractor documenting the stage of construction at the current time.
3. If proposed construction costs have increased over ten (10%) percent please provide information as an attachment to this form. Please note that such an overrun could require additional action before the Agency. - N/A

**B. NON-CONSTRUCTION PROJECTS**

1. Anticipated date of service implementation, acquisition or operation of the facility or equipment as certified.  
2-17-2013
2. Provide written confirmation from the institutional representative verifying the occupancy/opening date for the service, equipment, or facility.

*Say Jolly*  
Signature of Authorized Agent or Chief Operating Officer

5/31/13  
Date

October 24, 2014

2:57 pm



May 8, 2013

Mr. Danny Edsell  
Vice President  
Covenant Health Properties  
280 Fort Sanders West Blvd Ste 214  
Knoxville, TN 37922-3363

RE: RCI Project No. 11009 – Roane Medical Center, CN1101-001A

Dear Mr. Edsell,

This letter is to confirm the above referenced project is complete. The State Department of Health Final Life Safety Inspection and Licensing Survey has been performed on December 4th – 7th, 2012.

If you have any questions, don't hesitate to contact this office.

Very truly yours,

RENTENBACH CONSTRUCTORS INC.

A handwritten signature in black ink, appearing to read 'F. Holland', is written over the printed name.

Fletcher Holland  
Project Manager

Ecc: Ms. Gaye Jolly

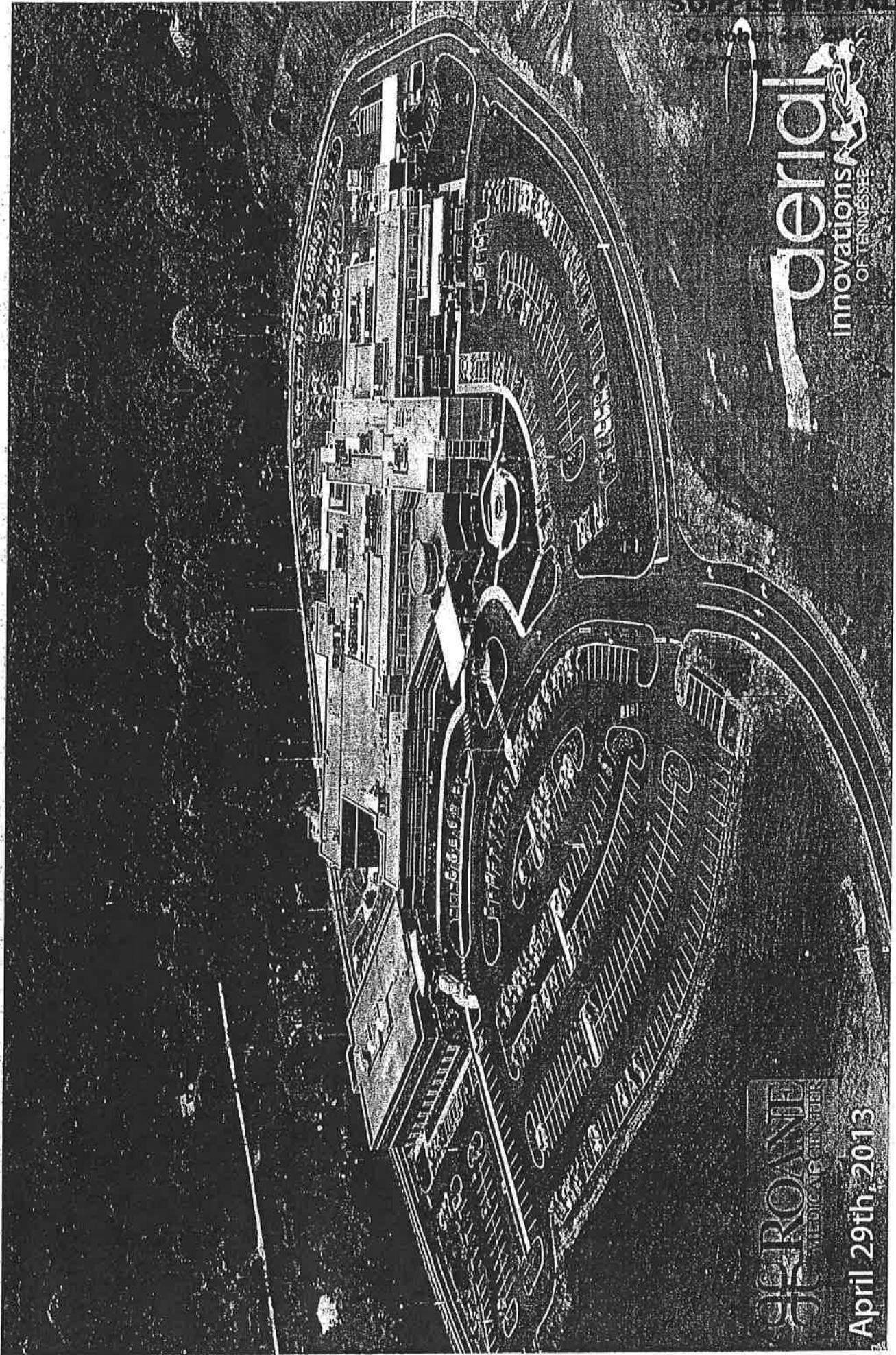


October 1st, 2013  
12:57 PM

period  
innovations  
OF TENNESSEE

HEROANE  
MEDICAL CENTER

April 29th, 2013



**Question 2**

## Health Care Facilities

**Licensed Facilities**

For more information, please contact:

Health Care Facilities: (615)741-7221 or 1-888-310-4650

**Current Listings:***Type* = Hospital *County* = HAMBLEN[Click here to return to the search page](#)**Total Facilities:2****Total Beds:302**

1. LAKEWAY REGIONAL HOSPITAL 726 MCFARLAND STREET MORRISTOWN, TN 37814 <i>Attn:</i> BRYAN CLYDE WOOD (423) 522-6004	Administrator: BRYAN CLYDE WOOD <i>Owner Information:</i> HOSPITAL OF MORRISTOWN, INC. 726 MCFARLAND ST. MORRISTOWN, TN 37814 (423) 522-6004	<i>Facility License</i> <i>Number:</i> 00000072 <i>Status:</i> Licensed <i>Number of Beds:</i> 0135 <i>Date of Last</i> <i>Survey:</i> 10/11/2007 <i>Accreditation</i> <i>Expires:</i> 01/23/2017 <i>Date of Original</i> <i>Licensure:</i> 07/01/1992 <i>Date of Expiration:</i> 06/18/2015
2. MORRISTOWN-HAMBLEN HEALTHCARE SYSTEM 908 WEST FOURTH NORTH STREET MORRISTOWN, TN 37816-1178 <i>Attn:</i> GORDON E. LINTZ (423) 492-9000	Administrator: GORDON E. LINTZ <i>Owner Information:</i> MORRISTOWN-HAMBLEN HOSPITAL ASSOC. 908 W. FOURTH NORTH ST. MORRISTOWN, TN 37814 (423) 586-4231	<i>Facility License</i> <i>Number:</i> 00000073 <i>Status:</i> Licensed <i>Number of Beds:</i> 0167 <i>Date of Last</i> <i>Survey:</i> 01/07/2009 <i>Accreditation</i> <i>Expires:</i> 11/04/2014 <i>Date of Original</i> <i>Licensure:</i> 07/01/1992 <i>Date of Expiration:</i> 04/24/2015



# TENNESSEE DEPARTMENT OF HEALTH

Health Statistics  
2nd Floor, Andrew Johnson Tower  
710 James Robertson Parkway  
Nashville, TN 37243  
Telephone: (615) 741-1954 - Fax: (615) 253-1688

## JOINT ANNUAL REPORT OF HOSPITALS

2013

Schedule	Description	Page Number
A.	Identification	2
B.	Classification	3
C.	Accreditations and Approvals	5
D.	Services	6
E.	Financial Data	18
F.	Beds and Bassinets	22
G.	Utilization	24
H.	Psychiatric, Chemical Dependency	32
I.	Emergency Department	36
J.	Personnel	39
K.	Medical Staff	40
L.	Perinatal	41
M.	Nursing Survey	42
N.	Health Care Plans	43

TENNESSEE DEPARTMENT OF HEALTH  
JOINT ANNUAL REPORT OF HOSPITALS

2013

## SCHEDULE A - IDENTIFICATION\*

1. Name of Hospital Morristown - Hamblen Healthcare System Federal Tax I.D. # 62-0545814  
Did your facility name change during the reporting period? ☐ YES ☒ NO  
County Hamblen
2. Address of Street 908 West 4th North Street State Tennessee Zip 37814  
Facility City Morristown
3. Telephone Number (423) 492-9000  
Area Code Number
4. Name of Chief Executive Officer Gordon First Name Lintz Last Name  
Signature of Chief Executive Officer \_\_\_\_\_
5. Name of person(s) coordinating form completion Gail Wilson  
Telephone Number if different than above (865) 374-3211 Area Code Number
6. 167 Office Use Only
7. Reporting period used for this facility:  
Beginning Date 01/01/2013 Ending Date 12/31/2013
8. 365 Office Use Only
9. Does your hospital own or operate or have other hospitals licensed as satellites of your hospital? ☐ YES ☒ NO  
If yes, please complete the following.

NAME OF HOSPITAL	STATE ID	SATELLITE	OWN	OPERATE	OWN AND OPERATE
1 _____	_____	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2 _____	_____	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
3 _____	_____	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
4 _____	_____	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
5 _____	_____	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

SCHEDULE F - BEDS AND BASSINETS\*

1. PLEASE GIVE THE NUMBER OF:

- A. TOTAL LICENSED ADULT AND PEDIATRIC BEDS AS OF THE LAST DAY OF THE REPORTING PERIOD (exclude beds in a sub-acute unit that are licensed as nursing home beds) 167
- B. The number of adult and pediatric staffed beds set up, staffed and in use as of the last day of the reporting period. 159
- C. NEWBORN NURSERY BASSINETS AS OF THE LAST DAY OF THE REPORTING PERIOD 12
- D. Licensed Beds that were not staffed at any time during the reporting period. 6

2. STAFFED ADULT, PEDIATRIC, AND NEONATAL BEDS (exclude newborn nursery, include neonatal care units):

Was there a temporary or a permanent change in the total number of beds set up and staffed during the period? ☒ YES ☐ NO

If yes, give beds added or withdrawn (show increase by + and decrease by -) and date of change.

Bed change (+ or -) -23 Bed change (+ or -) 23 Bed change (+ or -) 0 Bed change (+ or -) 0

Date: 04/20/2013 Date: 12/09/2013 Date:          Date:         

3 SWING BEDS:

A. Does your facility utilize swing beds? ☐ YES ☒ NO If yes, number of Acute Care beds designated as Swing Beds. 0

B. PLEASE SPECIFY THE FOLLOWING FOR BEDS WHEN USED FOR LONG TERM SKILLED OR INTERMEDIATE CARE:

(How many admissions and how many days did you provide in the following categories?)

INTERMEDIATE CARE		ADMISSIONS	PATIENT DAYS
Private Pay		0	0
Other		0	0
Total		0	0

SKILLED CARE		ADMISSIONS	PATIENT DAYS
Commercial		0	0
Blue Cross		0	0
Medicare		0	0
Private Pay		0	0
Other		0	0
Total		0	0

## SCHEDULE F - BEDS AND BASSINETS (continued)\*

## 4. A. Number of Beds Set Up and Staffed on a typical day

SERVICE	BEDS
Medical	0
Surgical	0
Medical/Surgical	56
Obstetrics	7
Gynecological	0
OB/GYN	32
Pediatric	12
Eye	0
Neonatal Care	0
Intensive Care (excluding Neonatal)	20
Orthopedic	20
Urology	0
Rehabilitation	0
Chronic/Extended Care	0
Pulmonary	0
Psychiatric	12
Psychiatric specifically for Children and Youth under age 18	0
Psychiatric specifically for Geriatric Patients	12
Chemical Dependency	0
Chemical Dependency specifically for Children and Youth under age 18	0
Chemical Dependency specifically for Geriatric Patients	0
Swing Beds (for long term skilled or intermediate care)	0
Other, specify	0
Unassigned	0
TOTAL	159

## B. Number of Patients in hospital on a typical day. Exclude normal newborns (See Instructions), long term skilled or intermediate patients. 82

## 5. OBSERVATION BEDS

- A. Do you use inpatient staffed beds for 23-hour observation? ☒ YES ☐ NO If yes, number of beds 159
- B. Do you have beds assigned to dedicated 23-hour observation unit? ☐ YES ☒ NO If yes, number of beds 0
- C. Do you have beds in a "same-day-surgery" unit that are used for both same-day surgery and 23-hour observation? ☐ YES ☒ NO  
If yes, number of beds 0

**Question 8**



**Supplemental Attachment: Question 8****State Health Plan Principles**

1. The purpose of the State Health Plan is to improve the health of Tennesseans.

- a. How will this proposal protect, promote, and improve the health of Tennesseans over time?

The project proposes use of an existing vendor-owned mobile lithotripsy system operating within the region that has significant open capacity available to support this needed project. The proposed project will help MHH and its growing medical staff better serve many patients who present with the painful diagnosis of kidney stones.

The project represents an efficient, orderly, and effective way to relieve significant time and travel burdens for a significant and growing number of patients who seek care, and relief from acute pain, related to kidney stones. The proposed project provides an important clinical tool needed by the hospital's growing medical staff and improves local access for community physicians and their patients. The project will improve the health of Tennesseans over time through high quality care, patient satisfaction, and the alleviation of acute pain and suffering.

- b. What health outcomes will be impacted and how will the applicant measure improvement in health outcomes?

ESWL procedures provide a safe, effective, and less-invasive clinical alternative to surgical procedures for many patients with kidney stones – resulting in high levels of patient care, quality, and satisfaction, that are measured and publicly reported by MHH and other hospitals.

ESWL procedures typically yield very positive clinical outcomes. The proposed project will improve access to lithotripsy services for patients and physicians within the project service area, reduce unnecessary patient burdens (i.e. time, suffering, and travel expense) related to lithotripsy case outmigration, and help MHH better coordinate needed patient care services locally in an optimal and orderly manner. The project will improve lithotripsy accessibility, use, and benefit within the region by initiating lithotripsy services at the well-known MHH campus. Like other clinical services at MHH, the ESWL services will be subject to the ongoing quality and service performance and training programs developed for physicians, leaders, and staff of the MHH Surgery Department and Emergency Department.

- c. How does the applicant intend to act upon available data to measure its contribution to improving health outcomes?

The proposed MHH lithotripsy service will be operated as part of the hospital's surgical department – and will be linked closely to operations of both physician practices in the service area and the hospital's emergency department. The ESWL service will be integrally linked to all hospital inpatient and outpatient quality, safety, service, and efficiency performance metrics – so will be monitored and managed for performance improvement over time to improve patient care and community health outcomes.

MHH will continue to support the State of Tennessee's goals and principles for "*achieving better health*" through ongoing accountability, public data reporting, peer review, outcomes monitoring, and other patient care quality assurances so that it's patients will "*have confidence that the quality of health care is continually monitored and standards are adhered to...*" in a manner consistent to the State Health Plan.

2. Every citizen should have reasonable access to health care.
  - a. How will this proposal improve access to health care? You may want to consider geographic, insurance, use of technology, and disparity issues (including income disparity), among others.

The primary goal of the proposed project is to improve access to ESWL services for both patients and physicians in the project service area by initiating the mobile service at MHH in an orderly and efficient manner. Consistent with the community-oriented mission of MHH, the hospital seeks to strengthen its historical commitment and recognized value as a leading provider of high quality patient care for the people who reside within region. The proposed project promotes this important planning goal by assuring continued and improved access to this needed clinical technology for all patients in the region. The proposed ESWL service will allow MHH to reduce patient burdens while improving operational efficiencies, patient and physician satisfaction, and overall continuum of care coordination.

The proposed mobile lithotripsy project will enhance convenience, access, and technology for patients living and working within the project service area that is marked by a growing and aging population – and relatively high levels of TennCare enrollment and poverty. According to the Tennessee Department of Health Website, each county of the proposed MHH ESWL project service area is considered a "Medically Underserved Areas" (MUA) – and therefore may warrant special consideration considering the significant outmigration to other areas of the state for this service.

The initiation of mobile lithotripsy services at MHH reflects an economically feasible approach to expanding access to needed services for the community. The lithotripsy services of MHH will be open and accessible to all patients and any referring physician in the region. Like all MHH services, this project will be accessible to all patients in the region since MHH is a contracted provider with all area TennCare MCOs and has a long history of serving patients regardless of race, ethnicity, gender, age, or income level. The project addresses evolving community needs and the expressed opinions of providers who serve patients from the region.

- b. How will this proposal improve information provided to patients and referring physicians?

Approval of the proposed ESWL service will enhance the array of clinical tools available for the MHH Medical Staff on the hospital campus – and will allow a significant number of MHH kidney stone patients to have the procedure performed sooner and closer to home. This project seeks to utilize an existing medical resource in the service area in a manner that is orderly, efficient, and collaborative – and that enhances patient access, choice, and convenience. Such improved access will provide a platform for ongoing patient and community education regarding care options – and will allow MHH to educate its referring physicians about improved access to the service at MHH through focused sharing of information.

Clinical information for most procedures performed at MHH is electronically transmitted to the East Tennessee Health Information Network (etHIN). etHIN is a regional health information network that provides electronic access to patient information by authorized participating health care providers. This health care information network that is used by authorized providers in Anderson, Blount, Campbell, Claiborne, Cocke, Cumberland, Grainger, Greene, Hamblen, Jefferson, Knox, Loudon, McMinn, Monroe, Morgan, Roane, Scott, Sevier, and Union to improve patient outcomes and helps to potentially lower the cost of care.

- c. How does the applicant work to improve health literacy among its patient population, including communications between patients and providers?

MHH has a strong history of promoting health awareness and education across its service area. For many years, MHH has engaged men, women, and children in the region with key health issues and wellness promotion.

MHH has also been an active advocate for both health literacy and literacy in general within the region. For example, MHH was the first hospital in the Tennessee to partner with the *Imagination Library* to promote literacy within the community, starting with its youngest patients. Today, every baby born at MHH will receive its first book from MHH (paid for by MHH) – and then the child is enrolled in the *Imagination Library Program* that will provide one book a month to the child throughout their childhood. Today, five other Tennessee hospitals have joined this partnership as well.

3. The State's health care resources should be developed to address the needs of Tennesseans while encouraging competitive markets, economic efficiencies, and the continued development of the State's health care system.

- a. How will this proposal lower the cost of health care?

This CON application seeks approval to initiate lithotripsy services and operate a vendor-owned mobile lithotripsy device that currently exists in the service area. The proposed equipment for the project is a clinically appropriate and proven lithotripsy unit that has open capacity available to meet the needs of MHH, its medical staff, and its patients for the foreseeable future. Moreover, the proposed arrangement to make mobile lithotripsy equipment available at MHH allows provider flexibility, and represents a unique opportunity for orderly and efficient collaboration within the service area.

Many patients are currently driving over one hour each way to receive lithotripsy services outside the service area. Increasing access to lithotripsy services in the region is the most practical, cost-effective, efficient, and orderly way to introduce a new lithotripsy service on site at MMH. The project seeks to utilize (i.e. share) medical equipment that already exists within the service area in a manner supported by the existing vendor, that will not be opposed by the only existing provider of mobile lithotripsy services within Hamblen County, and that requires no capital outlay by MHH, it's parent company, or it's medical staff. Additionally, ESWL services can provide a cost-effective and safe alternative to other care options.

- b. How will this proposal encourage economic efficiencies?

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This project represents a unique opportunity for competing hospitals to share an existing medical resource that is operational and underutilized in the service area to meet community needs. As outlined elsewhere in the original CON application and supplemental materials, the commitments and flexibility of a trusted ESWL vendor have created a platform that will allow a working arrangement that will encourage economic efficiencies for both hospitals. The proposed ESWL equipment-sharing arrangement should support the patient care operations and medical staff needs of both hospitals for the foreseeable future.

- c. What information will be made available to the community that will encourage a competitive market for health care services?

Information about the MHH ESWL service will be communicated to physicians and residents in the service area as appropriate so key stakeholders will be aware of the improved access to an important clinical resource in the region. The proposed project will serve any and all patients needing lithotripsy procedures within the region. Moreover, the project will provide another choice for patients who need high quality, efficient, and convenience access to ESWL procedures. The project will especially benefit patients in the service area who otherwise might have to travel to another provider outside the region for care.

4. Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers.
  - a. How will this proposal help health care providers adhere to professional standards?

MHH will continue to support the State of Tennessee's goals and principles for "*achieving better health*" through ongoing accountability, public data reporting, peer review, outcomes monitoring, and other patient care quality assurances so that it's patients will "*have confidence that the quality of health care is continually monitored and standards are adhered to...*" in a manner consistent to the State Health Plan.

The MHH ESWL service will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements. The service will be provided under the clinical oversight of a board certified urologist. Moreover, qualified employees of the MHH Surgery Department will manage routine ESWL procedures and any emergency procedures or related issues in conformity with accepted medical practice and standards of care. If the CON project is approved, MHH will develop and implement appropriate Policies and Procedures for ESWL services.

All ESWL procedures will be performed in accordance with appropriate clinical protocols and initiated under the direction of appropriately certified or licensed medical personnel. MHH and physician leadership will establish and/or follow appropriate ESWL guidelines in conjunction with the established lithotripsy operations of other Covenant Health affiliates.

Board certified urologists and/or other appropriately licensed physicians with appropriate training and certifications will provide overall patient care supervision to ensure that applicable clinical performance standards are met for all ESWL procedures.

As outlined elsewhere within this CON application, MHH meets the licensing and accreditation requirements of the State of Tennessee, The Joint Commission, CMS, and others.

- b. How will this proposal encourage continued improvement in the quality of care provided by the health care workforce?

All ESWL procedures will be performed in accordance with appropriate clinical protocols and initiated under the direction of appropriately certified or licensed medical personnel. MHH will establish and/or follow appropriate ESWL guidelines in conjunction with the established lithotripsy operations of other Covenant Health affiliates.

Board certified urologists and/or other appropriately licensed physicians with appropriate training and certifications will provide overall patient care supervision to ensure that applicable clinical performance standards are met for all ESWL procedures. Additionally, the ESWL equipment vendor will provide ongoing training for all clinical and support staff involved with the project.

Like other clinical services at MHH, the ESWL services will be subject to the ongoing quality and service performance and training programs developed for physicians, leaders, and staff of the MHH Surgery Department and Emergency Department.

5. The state should support the development, recruitment, and retention of a sufficient and quality health care workforce.\*
  - a. How will this proposal provide employment opportunities for the health care workforce?

MHH and Covenant Health have a proven track record of finding, hiring, and developing excellent clinical staff across service lines in conjunction with affiliated physicians. This project will provide another opportunity to develop existing employees – and to create work opportunities for future employees.

Covenant Health affiliated entities, including MHH, have a strong history of training many students in clinical areas that enhance community healthcare within East Tennessee. It is likely that the proposed project will benefit from and enhance ongoing training efforts and relationships with training programs in the region. In practical ways, the current and future healthcare workforce in the region will benefit from the project.

- b. How will this proposal complement the existing Service Area workforce?

The project will complement the existing service area workforce by providing a platform for further training and development of clinical and support staff – as well as by providing enhanced opportunities for employees to learn new skills while working with medical specialists as they serve patients. Additionally, the ESWL equipment vendor will provide ongoing training for MHH employees involved with the project.

**October 24, 2014****2:57 pm**

## **Question 9**

**Anton M. Allen, MD**

Associate Professor, The University of Tennessee Graduate School of Medicine

**Clinical Area of Interest**

Musculoskeletal Radiology

**Education**

Undergraduate – College of William and Mary

Medical School – Medical College of Virginia

Residency – Diagnostic Radiology, Medical University of South Carolina

Fellowship – Musculoskeletal Radiology, Bowman Gray School of Medicine

**Board Certification**

American Board of Radiology

**Yong C. Bradley, MD**

Associate Professor, The University of Tennessee Graduate School of Medicine

**Clinical Area of Interest**

Nuclear Medicine

**Education**

Medical – Medical College of Georgia, Augusta, GA

Residency - Diagnostic Radiology, Tripler Army Medical Center, Honolulu, HI

Fellowship - Nuclear Medicine, Brooke Army Medical Center, San Antonio, TX

**Board Certification**

**James W. Boyd, MD**

Assistant Professor, The University of Tennessee Graduate School of Medicine

**Clinical Area of Interest**

Neuroradiology

**Education**

Undergraduate – Memphis State University

Medical School – University of Tennessee Center for the Health Sciences

Internship – University of Iowa, Methodist Hospital

Residency – Methodist Hospital

**Board Certification**

American Board of Radiology

Certificate of Added Qualification – Neuroradiology

**Stephen Brown, MD**

Assistant Professor, The University of Tennessee Graduate School of Medicine

**Clinical Area of Interest**

Neuroradiology

**Education**

Undergraduate – Towson State University  
 Medical School – Chicago Medical School  
 Internship – Walter Reed Army Medical Center  
 Residency – Walter Reed Army Medical Center  
 Fellowship – Johns Hopkins University Hospital, George Washington University Hospital  
**Board Certification**  
 American Board of Radiology

**Paul Campbell, MD**

Associate Professor, The University of Tennessee Graduate School of Medicine

**Clinical Area of Interest**

Neuroradiology

**Education**

Undergraduate – The University of Tennessee, Knoxville, TN  
 Medical School – The Johns Hopkins University School of Medicine  
 Internship – York Hospital, York Pennsylvania  
 Residency – Diagnostic Radiology, The Johns Hopkins University School of Medicine  
 Fellowship – Diagnostic Neuroradiology Fellowship, The Johns Hopkins University School of Medicine

**Board Certification**

American Board of Radiology

**Dana Fathy, M.D., PhD**

Assistant Professor, The University of Tennessee Graduate School of Medicine

**Clinical Area of Interest**

Body Imaging, Emergency/Trauma Radiology

**Education**

Undergrad – University of Tennessee  
 Medical – Texas Tech School of Medicine  
 Intern and Residency – UT Graduate School of Medicine Knoxville

**Board Certification**

American Board of Radiology

**Andrew Ferrell, MD**

Assistant Professor, The University of Tennessee Graduate School of Medicine

**Clinical Area of Interest**

NeuroInterventional Radiology

**Education**

Medical School - Medical University of South Carolina, Charleston, South Carolina  
 Internship - Medical University of South Carolina, Charleston, South Carolina  
 Residency - University of Alabama at Birmingham, Birmingham, Alabama  
 Fellowship - Duke University, Durham, North Carolina



**Board Certification**

The American Board of Radiology

**Laura K. Findeiss, MD**

Associate Professor and Chair, The University of Tennessee Graduate School of Medicine

**Clinical Area of Interest**

Peripheral arterial disease, Critical Limb Ischemia, Aneurysms, Vascular Anomalies and Malformations, Venous Disease, Cancer Therapy

**Education**

Undergraduate – George Washington University International Relations Washington, DC

Medical School – University of Pittsburgh Pittsburgh, PA

Residency – General Surgery University of Tennessee Medical Center Knoxville, TN

Residency – Diagnostic Radiology Virginia Mason Medical Center Seattle, WA

Fellowship – Fellowship in Vascular and Interventional Radiology University of Washington Seattle, WA

**Board Certification**

American Board of Radiology (Diagnostic Radiology and Vascular and Interventional Radiology)

American Board of Vascular Medicine (Endovascular Medicine)

Association of Registered Diagnostic Medical Sonographers, Registered Physician in Vascular Interpretation

**Judson R. Gash, MD**

Associate Professor, The University of Tennessee Graduate School of Medicine

**Clinical Area of Interest**

Virtual Colonoscopy and Coronary CT Angiography

**Education**

Undergraduate – College of Charleston

Medical School – University of South Carolina School of Medicine

Residency – Diagnostic Radiology, Bowman Gray School of Medicine

**Board Certification**

American Board of Radiology

**Kathleen B. Hudson, MD**

Associate Professor, The University of Tennessee Graduate School of Medicine

Director, Diagnostic Radiology Residency Program, The University of Tennessee Medical Center

**Clinical Area of Interest**

Mammography

**Education**

Undergraduate – McNeese State University

Graduate – Master of Education in Administration and Supervision, McNeese State University

Medical School – Louisiana State University Medical Center, Shreveport, LA

Internship – Louisiana State University Medical Center, Shreveport, LA

Residency – Diagnostic Radiology, The University of Tennessee Medical Center

**Board Certification**

American Board of Radiology

**Steven P. Knight, MD**

Assistant Professor, The University of Tennessee Graduate School of Medicine

**Clinical Area of Interest**

General Radiology, Cardiac Imaging, Thoracic Imaging, PET

**Education**

Undergraduate – University of Tennessee – Knoxville 87-93

Medical School – University of Tennessee – Memphis Health Sciences Center 94-98

Internship – University of Tennessee Medical Center – Knoxville 98-99

Residency – Medical Center-Knoxville 99-03

Fellowship – University of Tennessee Medical Center – Knoxville 03-04

**Board Certification**

American Board of Radiology 2003

**Peter Kvamme, MD**

Assistant Professor, The University of Tennessee Graduate School of Medicine

**Clinical Area of Interest**

Interventional & NeuroInterventional Radiology and Nuclear Medicine

**Education**

Undergraduate – Saint Olaf College

Medical School – Tulane University School of Medicine

Internship – Categorical General Surgery, University of Texas Medical Branch

Residency – Nuclear Medicine, Baylor College of Medicine, Diagnostic Radiology, St. Francis Medical Center

Fellowship – Vascular and Interventional Radiology, Louisiana State University Medical Center; Interventional Neuroradiology, The Johns Hopkins Hospital

**Board Certification**

American Board of Radiology

**Geoffrey Laing, MD**

Assistant Professor, The University of Tennessee Graduate School of Medicine

**Clinical Area of Interest**

Breast imaging, Gastrointestinal radiology, Spine imaging and Pain management

**Education**

Undergraduate – University of Arizona, Biochemistry

Medical School – University of Texas Medical Branch

Internship – University of Texas Health Science Center, Internal Medicine

Residency – University of Texas Health Science Center, Diagnostic Radiology

Fellowship – University of Texas Health Science Center, Abdominal Imaging

**Board Certification**

American Board of Radiology, 2006

**Garnetta Morin-Ducote, MD**

Associate Professor, The University of Tennessee Graduate School of Medicine

**Clinical Area of Interest**

General Radiology, Mammography, and Breast MRI

**Education**

B.S. Biochemistry, Virginia Tech, 1979

M.S. Microbiology, LSU Medical Center, New Orleans, 1981

M.D. Medicine, LSU Medical Center, New Orleans, 1991

M.D. Transitional Year, LSU Medical Center, New Orleans

M.D. Radiology, UT Medical Center, Knoxville, 1996

**Board Certification**

American Board of Radiology

**Jeffrey W. Peeke, M.D.**

Assistant Professor, The University of Tennessee Graduate School of Medicine

**Clinical Area of Interest**

Cardiac CTA and MRI

**Education**

Undergraduate – Southern Adventist University

Medical School – Loma Linda University

Internship – University of Tennessee Medical Center

Residency – University of Tennessee Medical Center

Fellowship – UM Cardiothoracic Imaging

**Board Certification**

American Board of Radiology

**Peter T. Petruzzi, MD**

Assistant Professor, The University of Tennessee Graduate School of Medicine

**Clinical Area of Interest**

Thoracoabdominal Imaging and Musculoskeletal Radiology

**Education**

Undergraduate – Birmingham Southern College

Medical School – University of South Alabama College of Medicine

Internship – Carraway Methodist Medical Center

Residency – University of South Alabama

Fellowship – Thoracoabdominal Imaging, University of Virginia

**Board Certification**

American Board of Radiology

**Kenneth A. Rule, MD**

Professor, The University of Tennessee Graduate School of Medicine

**Clinical Area of Interest**

General Radiology and Ultrasonography

**Education**

Undergraduate – University of Tennessee, BA 1973-77

Medical School – University of Tennessee Center for Health Sciences, MD 1977-81

Internship – University of Tennessee Medical Center, Knoxville 1981-82

Residency – University of Kentucky, 1982-85

**Board Certification**

American Board of Radiology, 1985.

**John J. Snidow, MD**

Assistant Professor, The University of Tennessee Graduate School of Medicine

**Clinical Area of Interest**

Interventional Radiology

**Education**

Undergraduate – West Virginia University

Medical School – Marshall University School of Medicine

Residency – Diagnostic Radiology, Wayne State University

Fellowship – Vascular/Interventional Radiology, University of Iowa, Vascular/Interventional Radiology, Yale University

**Board Certification**

American Board of Radiology

American Board of Radiology, Vascular and Interventional Radiology

**Deanna Taylor-Gantte, MD**

Assistant Professor, The University of Tennessee Graduate School of Medicine

**Clinical Area of Interest**

Emergency & Oncology Radiology

**Education**

Undergraduate – University of Tennessee, Knoxville

Medical School – University of Tennessee, Memphis

Internship – Emergency Medicine, Indiana University, Indianapolis

Residency – Nuclear Medicine & Radiology Residencies at University of Tennessee Graduate School of Medicine, Knoxville

**Board Certifications**

American Board of Radiology and American Board of Nuclear Medicine

**Rong Zeng, MD**

Assistant Professor, The University of Tennessee Graduate School of Medicine

**Clinical Area of Interest**

**Musculoskeletal radiology**

**Education**

Undergraduate – The University of Texas at Arlington  
Medical School – The University of Texas A&M College of Medicine  
Internship – The University of Texas Health Sciences Center at Houston  
Residency – The University of Texas Health Sciences Center at San Antonio  
Fellowship – The University of Texas Health Sciences Center at San Antonio

**Board Certification**

Diagnostic Radiology by American Board of Radiology

**David E. Biddle, FNP**

**Family Nurse Practitioner**

**Clinical Area of Interest**

Interventional & NeuroInterventional Radiology

**Education**

Carson Newman College, East Tennessee State University

**Certification**

FNP: ANCC Board Certified

**Supplemental Attachment – Question 9.c.**

**Referral Urological Physicians in Service Area**

Physician Name	Specialty	Medical Staff Status	Address	Board Certification
Pickens, Ryan B., M.D.	Urology	Consulting	1928 Alcoa Hwy, Bldg B, Ste 222, 37920	Urology
Serbin, Philip, M.D.	Urology	Active	701 McFarland Street, 37814	Urology
White, Wesley M., M.D.	Urology	Consulting	1928 Alcoa Hwy, Bldg B, Ste 222, 37920	Urology
Woodworth, Bruce E., M.D.	Urology	Consulting	1932 Alcoa Hwy, Suite C-475, 37920	Urology

**Question 14**

**October 24, 2014****2:57 pm****Question 18**



**October 24, 2014****2:57 pm**

**Morristown-Hamblen  
Hospital Association  
Morristown, TN**

has been Accredited by



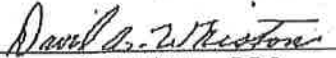
**The Joint Commission**

Which has surveyed this organization and found it to meet the requirements for the

**Ambulatory Health Care Accreditation Program**

**November 3, 2011**

Accreditation is customarily valid for up to 36 months.

  
David A. Whiston, D.D.S.  
Chairman of the Board

Organization ID #: 7881  
Print/Reprint Date: 05/14/12

  
Mark Chassin, M.D.  
President

The Joint Commission is an independent, not-for-profit, national body that oversees the safety and quality of health care and other services provided in accredited organizations. Information about accredited organizations may be provided directly to The Joint Commission at 1-800-994-6610. Information regarding accreditation and the accreditation performance of individual organizations can be obtained through The Joint Commission's web site at [www.jointcommission.org](http://www.jointcommission.org).



This reproduction of the original accreditation certificate has been issued for use in regulatory/payer agency verification of accreditation by The Joint Commission. Please consult Quality Check on The Joint Commission's website to confirm the organization's current accreditation status and for a listing of the organization's locations of care.

**October 24, 2014****2:57 pm**

May 8, 2012

Re: # 7881

CCN: #440030

Program: Hospital

Accreditation Expiration Date: November 04, 2014

Jeremy Biggs  
President/CAO  
Morristown-Hamblen Hospital Association  
P.O. Box 1178  
Morristown, Tennessee 37816-1178

Dear Mr. Biggs:

This letter confirms that your November 01, 2011 - November 03, 2011 unannounced full resurvey was conducted for the purposes of assessing compliance with the Medicare conditions for hospitals through The Joint Commission's deemed status survey process.

Based upon the submission of your evidence of standards compliance on December 21, 2011 and February 27, 2012 and the successful on-site Accreditation Follow-up event conducted on May 04, 2012, the areas of deficiency listed below have been removed. The Joint Commission is granting your organization an accreditation decision of Accredited with an effective date of May 04, 2012. We congratulate you on your effective resolution of these deficiencies.

§482.23 Condition of Participation: Nursing Services  
§482.24 Condition of Participation: Medical Record Services  
§482.41 Condition of Participation: Physical Environment  
§482.52 Condition of Participation: Anesthesia Services

The Joint Commission is also recommending your organization for continued Medicare certification effective May 04, 2012. Please note that the Centers for Medicare and Medicaid Services (CMS) Regional Office (RO) makes the final determination regarding your Medicare participation and the effective date of participation in accordance with the regulations at 42 CFR 489.13. Your organization is encouraged to share a copy of this Medicare recommendation letter with your State Survey Agency.

This recommendation also applies to the following location(s):

Advanced Women's Health Specialists  
1633 West Morris Blvd., Suite A, Morristown, TN, 37814

Morristown Hamblen Hospital Association  
d/b/a Morristown-Hamblen Healthcare System  
908 W. 4th North Street, Morristown, TN, 37814

[www.jointcommission.org](http://www.jointcommission.org)

**Headquarters**  
One Renaissance Boulevard  
Oakbrook Terrace, IL 60181  
630 792 5000 Voice

**October 24, 2014****2:57 pm**

Morristown Regional Diagnostic Center  
901 West Fourth North Street, Morristown, TN, 37814

Partial Hospitalization Program  
d/b/a Senior Support Program  
1111 Watercrest Street, Morristown, TN, 37814

Prompt Family Care  
1621 West Morris Boulevard, Morristown, TN, 37813

Prompt Family Care - Jefferson City  
1405 South Sizer Street, Suite A, Jefferson City, TN, 37760

Prompt Family Care - Sur (South)  
1050 Freshour Street, Suite A, Morristown, TN, 37813

Sleep Disorders Center  
924 West Fourth North Street, Morristown, TN, 37814

Surgery-Endoscopy Center of Morristown  
825 West Fifth North Street, Morristown, TN, 37814

Women's Health Specialists  
d/b/a Elite Women's Health Specialists  
609 McFarland Street, Morristown, TN, 37813

We direct your attention to some important Joint Commission policies. First, your Medicare report is publicly accessible as required by the Joint Commission's agreement with the Centers for Medicare and Medicaid Services. Second, Joint Commission policy requires that you inform us of any changes in the name or ownership of your organization, or health care services you provide.

Sincerely,

*Ann Scott Blouin RN, PhD*

Ann Scott Blouin, RN, Ph.D.  
Executive Vice President  
Accreditation and Certification Operations

cc: CMS/Central Office/Survey & Certification Group/Division of Acute Care Services  
CMS/Regional Office 4 /Survey and Certification Staff

**October 24, 2014****2:57 pm**

May 8, 2012

Jeremy Biggs  
President/CAO  
Morristown-Hamblen Hospital Association  
908 West Fourth North Street  
Morristown, TN 37814

Joint Commission ID #: 7881  
Program: Hospital Accreditation  
Accreditation Activity: Unannounced  
Accreditation Follow-up  
Accreditation Activity Completed: 05/04/2012

Dear Mr. Biggs:

The Joint Commission would like to thank your organization for participating in the accreditation process. This process is designed to help your organization continuously provide safe, high-quality care, treatment, and services by identifying opportunities for improvement in your processes and helping you follow through on and implement these improvements. We encourage you to use the accreditation process as a continuous standards compliance and operational improvement tool.

The Joint Commission is granting your organization an accreditation decision of Accredited for all services surveyed under the applicable manual(s) noted below:

Comprehensive Accreditation Manual for Hospitals

This accreditation cycle is effective beginning November 04, 2011. The Joint Commission reserves the right to shorten or lengthen the duration of the cycle; however, the certificate and cycle are customarily valid for up to 36 months.

Please visit [Quality Check®](#) on The Joint Commission web site for updated information related to your accreditation decision.

We encourage you to share this accreditation decision with your organization's appropriate staff, leadership, and governing body. You may also want to inform the Centers for Medicare and Medicaid Services (CMS), state or regional regulatory services, and the public you serve of your organization's accreditation decision.

Please be assured that The Joint Commission will keep the report confidential, except as required by law. To ensure that The Joint Commission's information about your organization is always accurate and current, our policy requires that you inform us of any changes in the name or ownership of your organization or the health care services you provide.

Sincerely,

Ann Scott Blouin, RN, Ph.D.  
Executive Vice President  
Accreditation and Certification Operations

**October 24, 2014****2:57 pm**

June 25, 2012

Gordon Lintz  
President/CAO  
Morristown-Hamblen Hospital Association  
908 West Fourth North Street  
Morristown, TN 37814

Joint Commission ID #: 7881  
Program: Ambulatory Health Care  
Accreditation  
Accreditation Activity: Measure of Success  
Accreditation Activity Completed: 06/25/2012

Dear Mr. Lintz:

The Joint Commission would like to thank your organization for participating in the accreditation process. This process is designed to help your organization continuously provide safe, high-quality care, treatment, and services by identifying opportunities for improvement in your processes and helping you follow through on and implement these improvements. We encourage you to use the accreditation process as a continuous standards compliance and operational improvement tool.

The Joint Commission is granting your organization an accreditation decision of Accredited for all services surveyed under the applicable manual(s) noted below:

- Comprehensive Accreditation Manual for Ambulatory Health Care

This accreditation cycle is effective beginning November 03, 2011. The Joint Commission reserves the right to shorten or lengthen the duration of the cycle; however, the certificate and cycle are customarily valid for up to 36 months.

Please visit Quality Check® on The Joint Commission web site for updated information related to your accreditation decision.

We encourage you to share this accreditation decision with your organization's appropriate staff, leadership, and governing body. You may also want to inform the state or regional regulatory services, and the public you serve of your organization's accreditation decision.

Please be assured that The Joint Commission will keep the report confidential, except as required by law. To ensure that The Joint Commission's information about your organization is always accurate and current, our policy requires that you inform us of any changes in the name or ownership of your organization or the health care services you provide.

Sincerely,

Mark G. Pelletier, RN, MS  
Chief Operating Officer  
Division of Accreditation and Certification Operations

**October 24, 2014**

**2:57 pm**

**Affidavit**

October 24, 2014

2:57 pm

OCT 24 '14 PM 2:53

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF KNOXNAME OF FACILITY: MORRISTOWN - HAMLEN HOSPITAL

I, MIKE RICHARDSON, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.

Mike Richardson V.P. STRATEGIC PLANNING  
Signature/Title & DEVELOPMENT

Sworn to and subscribed before me, a Notary Public, this the 23<sup>rd</sup> day of OCTOBER, 2014,  
witness my hand at office in the County of KNOX, State of Tennessee.

[Signature]  
NOTARY PUBLIC

My commission expires SEPTEMBER 11, 2017.

HF-0043

Revised 7/02







**CERTIFICATE OF NEED  
REVIEWED BY THE DEPARTMENT OF HEALTH  
DIVISION OF POLICY, PLANNING AND ASSESSMENT  
615-741-1954**

**DATE:** November 30, 2014

**APPLICANT:** Morristown-Hamblen Hospital  
908 West Fourth North Street  
Morristown, Tennessee 37814

CN1410-043

**CONTACT PERSON:** Mike Richardson, Vice President  
Strategic Planning and Development  
908 West Fourth North Street  
Morristown, Tennessee 37814

**COST:** \$328,900

In accordance with Section 68-11-1608(a) of the Tennessee Health Services and Planning Act of 2002, the Tennessee Department of Health, Division of Policy, Planning, and Assessment, reviewed this certificate of need application for financial impact, TennCare participation, compliance with *Tennessee's State Health Plan*, and verified certain data. Additional clarification or comment relative to the application is provided, as applicable, under the heading "Note to Agency Members."

**SUMMARY:**

The applicant, Morristown-Hamblen Hospital, located in Morristown, (Hamblen County), Tennessee, seeks Certificate of Need (CON) approval for the initiation of mobile extra corporeal shockwave lithotripsy services using a vendor-owned mobile lithotripsy unit for two (2) days per week on the hospital campus located at 908 West Fourth North Street, Morristown.

Morristown-Hamblen Hospital (MHH) is a 167-bed not-for-profit community hospital. On July 1, 2010, MHH became part of Covenant Health. Covenant Health is a Tennessee non-profit corporation, qualified under 501(c)(3) of the Internal Revenue Code, with its principal offices in Knoxville, Tennessee.

Covenant Health has one consolidated Board of Directors that governs operations including hospitals, behavioral health facilities, cancer treatment centers, various outpatient diagnostic and treatment centers, and several other healthcare related ventures. Covenant is the sole member of its non-profit subsidiaries and is the sole shareholder of its for-profit subsidiaries.

The applicant provides a list of hospital facilities currently operated by Covenant Health on page 3 of the application.

This application has been placed on the Consent Calendar. Tenn. Code Ann. § 68-11-1608 Section (d) states the executive director of Health Services and Development Agency may establish a date of less than sixty (60) days for reports on applications that are to be considered for a consent or emergency calendar established in accordance with agency rule. Any such rule shall provide that, in order to qualify for the consent calendar, an application must not be opposed by any person with legal standing to oppose and the application must appear to meet the established criteria for the issuance of a certificate of need. If opposition is stated in writing prior to the application being formally considered by the agency, it shall be taken off the consent calendar and placed on the next regular agenda, unless waived by the parties.

The total estimated project cost is \$328,900 and will be funded through operational cash flow. However, the applicant has access to sufficient cash reserves to complete and support the proposed project as needed.

### GENERAL CRITERIA FOR CERTIFICATE OF NEED

The applicant responded to all of the general criteria for Certificate of Need as set forth in the document *Tennessee's State Health Plan*.

#### NEED:

The applicant's primary service area is Hamblen County. The secondary service area includes Claiborne, Cocke, Grainger, and Jefferson Counties. The population projections for 2014 to 2017 are provided in the following chart. All five counties are medically underserved areas (MUA).

**Service Area Total Population Projections for 2014 and 2017**

County	2014 Population	2017 Population	% Increase or (Decrease)
Claiborne	32,604	33,110	1.6%
Cocke	36,762	38,143	3.8%
Grainger	23,111	23,513	1.7%
Hamblen	64,108	65,181	1.7%
Jefferson	53,729	56,054	4.3%
<b>Total</b>	<b>210,314</b>	<b>216,001</b>	<b>2.7%</b>

Source: *Tennessee Population Projections 2000-2020, 2013 Revision, and 2012 Joint Annual Report of Hospitals*, Tennessee Department of Health, Division of Health Statistics

As an important component of the TennCare provider in the applicant's designated service area, MHH serves all patients regardless of race, ethnicity, gender, age, and income level. MHH has a long history of commitment to ongoing investments in both clinical talent and medical technology needed to better serve the needs and wants of the patients and providers in the service area. This project seeks to expand access to mobile lithotripsy services in the area to benefit both patients and physicians in the service area.

MHH proposes to provide the lithotripsy service utilizing a mobile extra corporeal shockwave lithotripsy via a vendor-owned mobile unit two (2) days per week on the hospital campus. The applicant believes this project will not only improve access to lithotripsy service in the region but also enable MHH and its growing medical staff better serve the many patients in the area that have a diagnosis of kidney stones.

The proposed location is well-known, convenient, and accessible and represents an efficient, orderly, and effective way to relieve the time and travel burdens for a growing number of patients who need care for the acute pain related to kidney stones. MHH believes this project provides an important clinical tool and improves local access for community physicians and their patients.

The lithotripsy unit will be operated as part of the hospital's surgical department and will be closely linked to operations of both physician practices in the area and the hospital's emergency department. The applicant provides letters from physicians in Attachment B.I.a.

There is one full-time lithotripsy unit in the service area, located at Lakeway Regional Hospital. In 2011, 2012, and 2013, Lakeway reported utilization to HSDA of 18, 42, and 6 procedures each year, respectively. Lakeway's leadership team provided written confirmation that they do not oppose to this project. The letter from Lakeway Regional Hospital is provided in Attachment B.I.b.

The applicant projects 52 procedures in year one and 78 procedures in year two of the project. By year three, the applicant projects 104 procedures.

The Tennessee Department of Health, Division of Policy, Planning and Assessment calculated the need for lithotripsy procedures for each county in the service area. The total project need is 298 procedures for the service area.

HAMBLEN	65,181	90
COCKE	38,143	53
CLAIBORNE	33,110	46
GRAINGER	23,513	32
JEFFERSON	56,054	77
	<b>216,001</b>	<b>298</b>

#### **TENNCARE/MEDICARE ACCESS:**

The applicant participates in both the Medicare and TennCare/Medicaid programs. MHH has TennCare MCO contracts with United Healthcare Community Plan and BlueCare.

TennCare revenues for year one are estimated to be \$116,909 or 15% of gross revenues. Medicare revenues are estimated to be \$444,245 or 57% of gross revenues.

#### **ECONOMIC FACTORS/FINANCIAL FEASIBILITY:**

The Department of Health, Division of Policy, Planning, and Assessment has reviewed the Project Costs Chart, the Historical Data Chart, and the Projected Data Chart to determine they are mathematically accurate and the projections are based on the applicant's anticipated level of utilization. The location of these charts may be found in the following specific locations in the Certificate of Need Application or the Supplemental material:

**Project Costs Chart:** The Project Costs Chart is located on page 38 of the application. The total project cost is \$328,900.

**Historical Data Chart:** The Historical Data Chart is located in Supplement I, Additional information. The applicant reported 15,164, 15,189, and 14,657 admissions in 2011, 2012, and 2013, respectively. The applicant reported net operating revenues of (\$2,977,428), (\$1,626,284), and \$3,561,297 each year, respectively.

**Projected Data Chart:** The Projected Data Chart is located in Supplemental 1, Additional Information. The applicant projects 52 and 78 procedures in years one and two, respectively. The total net operating revenue in year one is projected to be \$50,404 and \$75,607 in year two of the project.

The applicant's projected average gross charge is \$14,988, with an average deduction of \$11,160, resulting in an average net charge of \$3,828. The HSDA equipment registry first quartile charge was \$9,029.86, the median charge was \$12,783.82, and the 3<sup>rd</sup> quartile charge was \$17,953.48. The applicant's average gross charge compares charges with recent HSDA lithotripsy services on page 22 of Supplemental 1.

MHH considered the alternative of doing nothing but determined this option was not acceptable to the MHH medical staff and community physicians due to the increasing demand for lithotripsy services at the MHH site and the significant burden of traveling out of the county for many patients who need lithotripsy services.

The applicant also considered acquiring a lithotripsy unit but rejected it due to the cost, would create unneeded, duplicative and competing capacity in the region, and would not utilize existing resources in a service area with open capacity to address needs through orderly equipment leasing through a reputable vendor.

No construction or renovation is required for this project.

**CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTHCARE:**

MHH provides all contracts, arrangements, managed care organizations, etc., on page 47 of the application.

The applicant states this project will have a positive effect because it expands access to a needed service, enhancing the clinical capabilities of not-for-profit hospital in Hamblen County. The location of the proposed unit will make scheduling easy and efficient, uses existing staff and infrastructure, and will be operated as a fully-integrated component of the MHH campus.

The project should not have a negative effect on the service area. The applicant reports it should improve mobile lithotripsy access in the region by initiating services at a location through utilizing an existing vender-owned unit that has been underutilized.

The proposed staffing for the project involves existing staff illustrated in the following chart with the percentage of time devoted to the lithotripsy unit services.

Surgery RN	0.5 FTE
Pre/post RN	0.5 FTE
Surgery tech	0.5 FTE
Office and logistics	0.5 FTE

MHH is licensed by the Tennessee Department of Health, Board for Licensing Healthcare Facilities and accredited by Joint Commission for ambulatory health care and hospital services.

**SPECIFIC CRITERIA FOR CERTIFICATE OF NEED**

The applicant responded to all relevant specific criteria for Certificate of Need as set forth in the document *Tennessee's State Health Plan*.

**CERTIFICATE OF NEED STANDARDS AND CRITERIA  
EXTRA-CORPOREAL SHOCK WAVE LITHOTRIPSY SERVICES****Standards and Criteria**

- 1. Determination of Need:** The need for ESWL services is determined by applying the following formula:

$$N = (U \times P) + O$$

N = number of ESWL services procedures needed in a Service Area;

U = latest available Tennessee use rate (number of procedures performed per 1,000 population in the state as determined by the Tennessee Department of Health);

P = projection of population (in thousands) in the service area as determined by the Tennessee Department of Health for Tennessee counties and the United States Census Bureau for non-Tennessee counties; and

O = the number of out-of-state resident procedures performed within the applicant's Service Area in the same time frame used to determine U based upon publically reported data. The applicant should document the methodology used to count volume in out-of-state resident procedures and, if different from the definition of "procedure" described in these standards and criteria, should distinguish out-of-state procedures from in-state cases.

The need shall be based upon the Service Area's current year's population projected three years forward.

The Tennessee Department of Health, Division of Policy, Planning and Assessment calculated the need for lithotripsy procedures for each county in the service area. The total project need is 298 procedures for the service area.

HAMBLEN	65,181	90
COCKE	38,143	53
CLAIBORNE	33,110	46
GRAINGER	23,513	32
JEFFERSON	56,054	77
	<b>216,001</b>	<b>298</b>

*The applicant projects the following:*

	<b>Year One 2015</b>	<b>Year Two 2016</b>	<b>Year Three 2017</b>
ESWL Procedures	<b>52</b>	<b>78</b>	<b>104</b>
ESWL Procedures per week	<b>1.0 x 52 wks</b>	<b>1.5 x 52 wks</b>	<b>2.0 x 52 wks</b>

- 2. Minimum Volume Standard:** Applicants proposing to acquire and operate an ESWL services unit must project a minimum utilization of at least 250 procedures per year by the third year of operation, based on full-time use of an ESWL unit. The applicant must also document and provide data supporting the methodology used to project the patient utilization. An application to provide ESWL services on a part-time basis shall convert its projected use to that of a full-time equivalent ESWL unit.

*The applicant's proposed unit is for 2 days equals:*

	<b>Year One 2015</b>	<b>Year Two 2016</b>	<b>Year Three 2017</b>
ESWL Procedures	<b>52</b>	<b>78</b>	<b>104</b>
ESWL Procedures per week	<b>1.0 x 52 wks</b>	<b>1.5 x 52 wks</b>	<b>2.0 x 52 wks</b>

*If this were a full time unit the applicant provided the following:*

	<b>Year One 2015</b>	<b>Year Two 2016</b>	<b>Year Three 2017</b>
ESWL Procedures	<b>182</b>	<b>273</b>	<b>364</b>

- 3. Current Service Area Utilization:** The applicant should document that all existing providers of ESWL services within the proposed Service Area each performed at least 300 ESWL procedures per year during the most recent 12 month period for which data are available. The utilization by ESWL units that operate on a part-time basis shall be converted to that of a full-time equivalent ESWL unit. To characterize existing providers located within Tennessee, the applicant should use data provided by the Health Services and Development Agency. To characterize providers located outside of Tennessee, the applicant should use publicly available data, if available, and describe in its application the methodology these providers use to count volume.

In addition, the applicant should provide the HSDA with a report of patient destination for ESWL services based on the most recent 12 months of publicly reported data. This report should list all facilities that provided ESWL services to residents of the proposed Service Area and the number of ESWL procedures performed on residents of the Service Area for

each facility. The Tennessee Department of Health will assist applicants in generating this report utilizing the HDDS.

*Lakeway Hospital is the only provider currently located in the service area. Lakeway is not providing 300 procedures per year (18, 42, and 6 procedures in 2011, 2012, and 2013).*

- 4. Adverse Impact on Existing Providers:** An application for ESWL services should not be approved if the new program will cause the annual caseload of existing ESWL programs within the Service Area to drop below an average of 300 procedures. The utilization by ESWL units that operate on a part-time basis shall be converted to that of a full-time equivalent ESWL unit. The patient origin study conducted for Standard 2, an analysis of patient origin data collected for Standard 3, and the referral data documented for Standard 3 should be used to determine whether such an adverse impact on existing providers is likely to occur.

*Lakeway Hospital is the only provider currently located in the service area. Lakeway is not providing 300 procedures per year (18, 42, and 6 procedures in 2011, 2012, and 2013). There should be no impact on this provider. The applicant is a sister hospital and of Lakeway and will not oppose.*

- 5. Adequate Staffing and Services:** The applicant should document a plan for recruiting and maintaining a sufficient number of qualified professional and technical staff to provide the ESWL services and must document the following:

- a. The existence of an active radiology service and an established referral urological practice;
- b. The availability within 90 minutes' drive time of acute inpatient services for patients who experience complications; and
- c. The fact that all individuals using the equipment meet the training and credentialing requirements of the American College of Surgeons' Advisory Council for Urology.

The applicant should also document an ongoing educational plan for all staff included in the ESWL services program.

*The applicant complies with these criteria.*

- 6. ESWL Equipment:** Only applications that provide for the provision of ESWL services using equipment that has been approved by the United States Food and Drug Administration for clinical use shall be approvable.

*The applicant complies with this criterion.*

- 7. Quality Control and Monitoring:** The applicant should identify and document its intention to participate in a data reporting, quality improvement, outcome monitoring, and peer review system that benchmarks outcomes based on national norms. The system should provide for peer review among professionals practicing in facilities and programs other than the applicant.

*The applicant complies with this criterion.*

- 8. Data Requirements:** Applicants should agree to provide the Department of Health and/or the HSDA with all reasonably requested information and statistical data related to the operation and provision of services and to report that data in the time and format

requested. As a standard of practice, existing data reporting streams will be relied upon and adapted over time to collect all needed information.

*The applicant agrees to comply.*

- 9. Transfer and/or Affiliation Agreements:** If an applicant is not a designated Level 1 trauma center, an applicant must document an acceptable plan for the development of transfer and/or affiliation agreements with hospitals in the service area (this criterion does not preclude the development of transfer agreements with facilities outside the applicant's Service Area).

*MHH provides a list of transfer agreements in Attachment C.1.1.1.9.*

- 10. Access:** In addition to the factors set forth in HSDA Rule 0720-11-.01 (1) (listing the factors concerning need on which an application may be evaluated), the HSDA may choose to give special consideration to an applicant:

a. That is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;

*Not applicable.*

b. That documents that the service area population experiences a prevalence and/or incidence of urinary stones or other clinical conditions applicable to extra-corporeal shock wave lithotripsy services that is substantially higher than the State of Tennessee average; or

*The applicant's service area has a higher ESWL use rate in all but one county than the State wide use rate. In addition, MHH physicians and its affiliated staff have referred one to two kidney stone patients a week and sometime 3 to 4 per week.*

c. That is a "safety net hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program.

*Not applicable.*